UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
KNOXVILLE DIVISION

UNITED STATES OF AMERICA *ex rel.* **[SEALED]**, and on behalf of the STATES of GEORGIA, TENNESSEE, and the COMMONWEALTH OF VIRGINIA, Plaintiff-Relator, v. **[SEALED]** Defendant.	Case Number: 3:20-cv-436/CLC/DCP **FILED UNDER SEAL** **DO NOT PLACE ON PACER** **COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT, AND STATE LAW COUNTERPARTS** **Jury Trial Demanded**

RELATOR'S SEALED QUI TAM COMPLAINT PURSUANT TO THE FEDERAL FALSE CLAIMS ACT, 31 U.S.C. § 3730 ET SEQ. AND STATE LAW COUNTERPARTS

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UNITED STATES OF AMERICA *ex rel.* K-VA-T LITIGATION PARTNERSHIP, LLP, and on behalf of the STATES of GEORGIA, TENNESSEE, and the COMMONWEALTH OF VIRGINIA, Plaintiff-Relator, v. K-VA-T FOOD STORES, INC, d/b/a FOOD CITY, Defendant.	Case Number: **FILED UNDER SEAL** **DO NOT PLACE ON PACER** **COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT, AND STATE LAW COUNTERPARTS** **Jury Trial Demanded**

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COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS UNDER 31 U.S.C. § 3729, *ET SEQ.*, AND STATE LAW COUNTERPARTS

1. On behalf of the United States of America ("United States"), the States of Georgia and Tennessee and the Commonwealth of Virginia (collectively, the "Whistleblower States"), Relator K-VA-T Litigation Partnership (hereinafter "Relator") hereby files this Complaint against K-VA-T Food Stores, Inc, d/b/a Food City (hereinafter "Food City" or "Defendant"), pursuant to the *qui tam* provisions of the federal False Claims Act and the State Whistleblower Statutes.[1] Relator further brings this action pursuant to the anti-retaliation provision of the federal FCA, 31 U.S.C. § 3730(h), to recover damages against Defendant for retaliating against Relator for his whistleblowing activity.

2. Relator brings this action against Food City under the False Claims Act and State Whistleblower Statutes for Defendant's violations of the Controlled Substances Act, 21 U.S.C. § 801, *et seq.* (the "CSA") its implementing regulations, 21 C.F.R. § 1301, *et seq.* and under Georgia, Kentucky, Tennessee, and Virginia state pharmacy laws and regulations. Those violations include: (a) knowingly dispensing controlled substances throughout Georgia, Kentucky, Tennessee, and Virginia without a valid prescription in violation of 21 U.S.C. § 842(a)(1); and (b) knowingly and intentionally distributing and dispensing controlled substances throughout Georgia, Kentucky, Tennessee, and Virginia outside the usual course of the professional practice of pharmacy, in violation of 21 U.S.C. § 841(a). Relator also seeks to recover monies that Defendant caused the Government Programs to pay for controlled substances dispensed at its pharmacies throughout

[1] 31 U.S.C. §§ 3729 *et seq.* ("FCA"); the Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 *et seq.*; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 *et seq.* (the aforementioned statutes referred to collectively as the "State Whistleblower Statutes").

Georgia, Kentucky, Tennessee, and Virginia that were medically unnecessary and/or lacked a legitimate medical purpose in violation of the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq.*, as well as State *qui tam* laws.

I. INTRODUCTION

3. The nation is experiencing a national public health emergency involving opioid abuse. The dispensing and distribution of controlled substances, including prescription opioid painkillers, without a legitimate medical purpose and outside the usual course of professional practice exacerbate this crisis. This crisis has touched, and continues to touch, nearly all American individuals and families in some way.

4. In addition to the opioid epidemic's human cost, the epidemic has had a monetary one as well. Besides financial impacts like the increased costs for health care, substance abuse treatment, and law enforcement, the cost of the epidemic has also been felt by government programs like Medicare, Medicaid, and other Federal and State programs (collectively, "Government Programs"). The Government Programs have paid for inappropriate opioid prescriptions dispensed throughout Georgia, Kentucky, Tennessee, and Virginia because Food City has intentionally and knowingly disregarded its duties under the law to properly vet prescriptions and ensure that it only dispensed drugs pursuant to a legal prescription and for a legitimate medical purpose.

5. Food City has both fueled and profited from this epidemic throughout Georgia, Kentucky, Tennessee, and Virginia by repeatedly dispensing controlled substances prone to abuse and diversion without a legitimate medical purpose and outside the usual course of professional medical practice.

6. Despite Relator reporting his concerns regarding illegal conduct to Food City management, nothing was ever done.

7. Even while rampant drug abuse and diversion was occurring at and around the Food City pharmacies throughout Georgia, Kentucky, Tennessee and Virginia, many Food City pharmacies filled all prescriptions presented at its pharmacies—regardless of validity—resulting in inappropriate and medically unnecessary prescriptions being filled and billed, the public health and public fisc be damned. Throughout Georgia, Kentucky, Tennessee and Virginia, Food City has repeatedly dispensed controlled substances prone to abuse and diversion without a legitimate medical purpose and outside the usual course of professional practice.

8. Thus, Food City has both fueled and profited from the opioid epidemic throughout Georgia, Kentucky, Tennessee, and Virginia by repeatedly dispensing controlled substances prone to abuse and diversion without a legitimate medical purpose and outside the usual course of professional practice.

9. Food City is subject to duties under the Controlled Substances Act ("CSA") and under Georgia, Kentucky, Tennessee, and Virginia state pharmacy laws and regulations to take special care before dispensing these addictive and dangerous drugs. These laws and regulations require Food City to (1) review each opioid prescription prior to dispensing and to make a determination that the prescription is both effective and valid; (2) ensure that each prescription for an opioid is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice; (3) refuse to dispense medication if there is reason to believe that the prescription was not issued for a legitimate medical purpose; and (4) provide effective systems, controls, and procedures to prevent abuse and diversion of opioids. Food City violated these duties of care by dispensing extremely large amounts of opioids from its retail

pharmacy stores throughout Georgia, Kentucky, Tennessee, and Virginia and in this District, as alleged in more detail below.

10. For example, Food City Store No. 674, located at 5941 Kingston Pike, Knoxville, Tennessee, bought nearly one million high-dose OxyContin pills in 2008 alone, third-most of all pharmacies in the nation.[2] Between 2006 and 2014, Food City No. 674 dispensed over 22 million dosages of opioids, enough opioids for 79 pills per year for each of the 31,064 men, women and children who live within five miles of this pharmacy.[3] Food City No. 674 was located next to Bearden Healthcare Associates, one of the largest and most notorious pain clinics in the state and owned by Drs. Frank and Janet McNiel. Not coincidently, the providers at this pain clinic prescribed extremely high volumes of both high dose OxyContin and Oxy 30.

11. Food City No. 674 captured the bulk of the oxycodone prescriptions from Bearden Healthcare Associates even though others, such as Wal-Mart, Walgreens, and CVS, stopped dispensing prescriptions for the pill mill doctors. Dr. Frank McNiel pled guilty on October 17, 2019 to prescribing high doses of opioids with no medical legitimacy, admitting he had written opioid prescriptions without evaluating patients and without obtaining medical records that would have justified the prescription of opioids.[4]

12. Pharmacies serve as the last line of defense between dangerous opioids and the public. For this reason, under the CSA and Georgia, Kentucky, Tennessee, and Virginia state

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[2] Joseph Walker, *A Tennessee Pharmacy Bought Nearly a Million High-Dose OxyContins in 2008*, Wall Street Journal (Sept. 19, 2019).

[3] Armand Emamdjomek, *et al.*, *How many pain pills went to your pharmacy?*, Washington Post (Feb. 25, 2020), https://www.washingtonpost.com/graphics/2019/investigations/pharmacies-pain-pill-map/.

[4] Press Release, Department of Justice, *Two East Tennessee Doctors Plead Guilty to Opioid Offenses* (Oct. 18, 2019), https://www.justice.gov/opa/pr/two-east-tennessee-doctors-plead-guilty-opioid-offenses.

pharmacy laws and regulations, a pharmacy's duty to use due care when filling prescriptions goes beyond simply following the prescription's directions. Pharmacies that are on notice of signs of abuse or diversion and any other red flags that the prescriptions are not medically appropriate may not simply robotically fill prescriptions. This is particularly true when prescriptions are unreasonable on their face because they are written in a quantity, frequency, or other manner that would cause a reasonable pharmacist to do additional investigation and due diligence. Food City did not fulfill these duties.

13. Food City was clearly on notice of red flags that should have caused its pharmacies throughout Georgia, Kentucky, Tennessee, and Virginia to investigate (and then reject) opioid prescriptions instead of filling them. Examples of such red flags include: (1) doctors who write unusually large amounts of opioid prescriptions when compared with similar practitioners in the area; (2) doctors who are under investigation by the DEA and/or state board(s) of medicine for inappropriate and/or medically unnecessary opioid prescribing; (3) early refills for opioid prescriptions; (4) prescriptions with unusual quantities, dosages, or combinations of opioids; (5) patients seeking to fill a prescription written for someone else; (6) multiple consumers appearing at or near the same time with opioid prescriptions from the same physician; (7) patients who drive long distances to have a prescription filled; (8) consumers who seek large volumes of controlled substances in the highest strength for each prescription type; (9) patients who appear to be creating cocktails with muscle relaxants or tranquilizers; or (10) consumers who pay large amounts of cash for opioid prescriptions rather than using some form of insurance.

14. Food City pharmacies throughout Georgia, Kentucky, Tennessee, and Virginia routinely overlooked numerous red flags and instead filled even what were clearly inappropriate opioid prescriptions. Food City could have—and was required to—leverage its network of 106

pharmacies throughout Georgia, Kentucky, Tennessee, and Virginia to combat the scourge of inappropriate and/or medically unnecessary opioid prescriptions. Instead of limiting the filling of inappropriate and medically unnecessary prescriptions, Food City has deliberately ignored the increasingly rampant prescribing abuse, refused to identify medically inappropriate or unnecessary prescriptions, and did not provide its individual pharmacy locations adequate training and tools to control opioid dispensing and to combat abuse and diversion.

15. Food City did next to nothing to reduce inappropriate dispensing, instead focusing on its profitability over any impact on Government Programs and the safety and wellbeing of the public.

16. Food City pharmacies throughout Georgia, Kentucky, Tennessee, and Virginia routinely filled opioid prescriptions with unresolved red flags of diversion, in violation of its duties under the CSA and state pharmacies laws and regulations.

17. Food City failed to train or instruct its employees with respect to proper policies and protocols to prevent diversion of opioids. This has had the direct, readily foreseeable (and intended) result of its pharmacies throughout Georgia, Kentucky, Tennessee, and Virginia continuing to fill prescriptions despite clear red flags of abuse and diversion.

18. Food City's failure to identify, monitor, detect, investigate, report, and/or refuse to sell, fill, or dispense inappropriate prescriptions of opioids also violated its duty to act reasonably in light of the serious and foreseeable harms associated with opioid abuse and diversion. Food City's failure to take reasonable steps to prevent opioid abuse and diversion is a direct and proximate cause of, and/or substantial factor contributing to, the diversion of prescription opioids in Georgia, Kentucky, Tennessee, and Virginia for consumption for non-medical, non-scientific purposes.

19. Food City knew that widespread abuse and diversion of opioids was occurring throughout Georgia, Kentucky, Tennessee, and Virginia (and in this District) at a staggering scale but turned a blind eye in order to earn higher profits. The foreseeable result of Food City's decision to continue dispensing vast quantities of opioids having no medical justification has led to widespread addiction, overdoses, death, harms to Government Programs, and the societal and economic harms that flow from prescription opioid abuse and diversion.

20. Food City is primarily a grocery store chain and saw its pharmacies purely as profit centers that could supplement, and in some cases keep alive, its grocery stores. But in order to ensure its pharmacies were profitable, Food City buried its head in the sand and ignored the blatantly illegal dispensing going on its pharmacies. It did not give its pharmacists any resources or support to stop illegal dispensing, but rather intentionally and actively insisted its pharmacists to increase their dispensing of opioids to help the bottom line. Food City's stunning abdication of its duty to prevent diversion from its pharmacies led to the widespread filling of inappropriate prescriptions as detailed herein.

21. According to one former employee who worked in the Food City headquarters in Abingdon, Virginia, President and Chief Executive Officer Steve Smith "was looking at sales dollars." Smith reviewed the monthly sales reports and discussed them during monthly corporate staff meetings. "He knew what stores were selling a lot of CIIs," this former employee said, adding Smith just ignored the rampant over-dispensing of CIIs at its pharmacies. "He's the owner of the company. It was his pharmacy. . . . But what do you do when the owner tells you that it'll all work out?"

22. Despite Food City pharmacies being subject to numerous fines and sanctions from government authorities, the arrests of the pill mill doctors that drove the demand for Food City's

illegal dispensing is the real reason that Food City's opioid dispensing has slowed in recent years. Food City still operates its pharmacies with nearly the same core of persons in charge of its pharmacy operations, many of whom are not pharmacists and have no pharmacy background whatsoever.

23. The conduct alleged herein is ongoing.

24. Food City also retaliated against Relator for his whistleblowing activity. After witnessing numerous blatant instances of violations of the Controlled Substances Act by his immediate supervisor and others working in his pharmacy, Relator complained regularly to his manager and other senior management at Food City. He later reported what he had seen to the Tennessee Board of Pharmacy.

25. As a result of his whistleblowing activity, Relator was fired and has suffered, and continues to suffer, severe reputational, financial and psychological harm.

II. JURISDICTION AND VENUE

26. According to 28 U.S.C. §§ 1331 and 1345, this District Court has original jurisdiction over the subject matter of this civil action since it arises under the laws of the United States—in particular, the FCA. In addition, the FCA specifically confers jurisdiction upon the United States District Court under 31 U.S.C. § 3732(b).

27. Pursuant to 28 U.S.C. § 1367, this District Court has supplemental jurisdiction over the subject matter of the claims brought pursuant to the false claims acts of the States because the claims are so related to the claims within this Court's original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

28. This District Court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a) because Defendant transacts business in this District and engaged in wrongdoing in this

District. Likewise, the FCA authorizes nationwide service of process and the Defendant has sufficient minimum contacts with the United States of America.

29. Venue is proper in this District under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b). Defendant has transacted business within this District, and acts proscribed by 31 U.S.C. § 3729 occurred in this District.

30. The Knoxville Division of the Eastern District of Tennessee is proper because Defendant has transacted business within the Knoxville Division of the Eastern District of Tennessee, and acts proscribed by 31 U.S.C. § 3729 occurred in locations within the Knoxville Division of the Eastern District of Tennessee such as Knoxville, Gatlinburg, Sevierville, Maryville, and Oliver Springs.

31. Relator is unaware of any public disclosure of the information or allegations that are the basis of the Complaint. If there has been a public disclosure, Relator is the original source of the information and allegations contained in this Complaint. Prior to the filing of this action, Relator voluntarily provided the United States Government and the States with material information supporting the false claims that are the subject of this Complaint.

32. The causes of action alleged herein are timely brought because of, among other things, efforts by the Defendant to conceal its wrongdoing in connection with the allegations made herein from the United States and the Whistleblower States.

III. THE PARTIES

A. Plaintiff/Relator

33. Plaintiff/Relator K-VA-T Litigation Partnership (hereinafter "Relator"), a Delaware limited liability partnership, brings this action on behalf of itself, the United States of America and the Whistleblower States. The registered office of Relator is located at 1925 Lovering

Avenue, Wilmington, Delaware 19806, and the name of the registered agent at such address is The First State Registered Agent Company.

34. Pursuant to Section 15-201(a) of the Delaware Revised Uniform Partnership Act, Relator is not distinct from its partners, and by virtue of employment with Food City, at all times material hereto had firsthand, personal knowledge of the false claims, statements, and concealments alleged herein.

35. Relator and at least one of its partners have direct knowledge of the conduct alleged in this Complaint and conducted an independent investigation to uncover false claims submitted to the United States and the Whistleblower States. Accordingly, Relator is an "original source" of the non-public information alleged in this Complaint within the meaning of the federal FCA and the state false claims acts.

B. K-VA-T Food Stores, Inc, d/b/a Food City

36. Defendant K-VA-T Food Stores, Inc, d/b/a Food City, is a supermarket chain with stores located in Georgia, Kentucky, Tennessee, and Virginia. K-VA-T Food Stores, Inc., is a privately held family and employee-owned corporation with its principal place of business at One Food City Circle, Abingdon, Virginia. With regard to the wrongful conduct alleged herein, K-VA-T Food Stores, Inc. shall be referred to herein as "Food City."

37. K-VA-T Food Stores, Inc. operates 139 retail outlets (124 Food City stores, seven Super Dollar Food Centers, three Wine & Spirits stores, and five convenience stores) in Georgia, Kentucky, Tennessee, and Virginia. The chain includes some 106 in-store pharmacies wholly owned by K-VA-T.[5]

[5]*See* Food City, "Find Your Local Store," https://www.foodcity.com/stores/find-a-store/.

38. Food City, including through its subsidiary and affiliated entities, operates a chain of retail pharmacies throughout Georgia, Kentucky, Tennessee, and Virginia, including in this District. Food City has sold billions of opioid drugs throughout Georgia, Kentucky, Tennessee, and Virginia during all relevant times material hereto that were inappropriate and/or medically unnecessary.

IV. THE OPIOID CRISIS IN THE U.S. AND IN GEORGIA, KENTUCKY, TENNESSEE AND VIRGINIA

39. Opioids are a class of drugs that range from pain relievers available legally by prescription—such as oxycodone, hydrocodone, codeine, morphine, and fentanyl—to illegal narcotics such as heroin. According to the Medicaid and CHIP Payment and Access Commission, "the origins of widespread prescription opioid use can be traced back to the 1990s."[6] That is when the medical profession began using pain as a so-called "fifth vital sign," and drug manufacturers heightened their marketing campaigns.

40. All opioids are chemically related and interact with opioid receptors on nerve cells in the body and brain. Opioid pain relievers are generally safe when taken for a short time and as prescribed by a doctor, but because they produce euphoria in addition to pain relief, they can be misused (taken in a different way or in a larger quantity than prescribed, or taken without a doctor's prescription). Regular use—even as prescribed by a doctor—can lead to dependence and, when misused, opioid pain relievers can lead to addiction, overdose incidents, and death.[7]

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[6] Medicaid & CHIP Payment Access Comm'n, *Report to Congress On Medicaid And CHIP: Chapter 2: Medicaid And The Opioid Epidemic* 79 (2017), https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf.

[7] NIH National Institute on Drug Abuse: Advancing Addiction Science, https://www.drugabuse.gov/drugs-abuse/opioids#summary-of-the-issue.

41. Deaths from prescription opioid overdoses quadrupled from 1999 to 2011,[8] as have opioid prescriptions, even though pain levels reported by Americans have not changed.[9] By 2013, drug overdoses were the nation's leading cause of deaths from injury, prompting one author to write: "The opioid epidemic . . . that has been ravaging and shortening lives from coast to coast is a new plague for our new century."[10]

42. Some 70,237 drug overdose deaths occurred in the United States in 2017. The age-adjusted rate of overdose deaths increased significantly by 9.6% from 2016 (19.8 per 100,000) to 2017 (21.7 per 100,000). Opioids—mainly synthetic opioids (other than methadone)—are currently the main driver of drug overdose deaths. Opioids were involved in 47,600 overdose deaths in 2017 (67.8% of all drug overdose deaths).[11]

43. Among the States with statistically significant increases in drug overdose death rates from 2016 to 2017 include Georgia, Kentucky, and Tennessee.[12]

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[8] Vikki Wachino, *CMCS Informational Bulletin: Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction* 1 (Jan. 28, 2016), https://www.medicaid.gov/federal-policy-guidance/downloads/cib-02-02-16.pdf.

[9] Ctrs. For Medicare & Medicaid Servs., Centers For Medicare & Medicaid Services (CMS), *Opioid Misuse Strategy 2016* 2 (Jan. 5, 2017), https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/CMS-Opioid-Misuse-Strategy-2016.pdf.

[10] Nicholas N. Eberstadt, *Our Miserable 21st Century*, COMMENTARY MAG. (Feb. 2017), https://www.commentarymagazine.com/articles/our-miserable-21st-century/.

[11] U.S. Ctrs. for Disease Control & Prevention, *Drug Overdose Deaths*, https://www.cdc.gov/drugoverdose/data/statedeaths.html.

[12] U.S. Ctrs. for Disease Control & Prevention, National Center for Health Statistics Multiple Cause of Death 1999–2017, *Wide-ranging Online Data for Epidemiologic Research* (CDC WONDER), (2019), https://wonder.cdc.gov/wonder/help/mcd.html.

44. Every day, more than 130 people in the United States die after overdosing on opioids.[13] The misuse of and addiction to opioids—including prescription pain relievers, heroin, and synthetic opioids such as fentanyl—is a serious national crisis that affects public health as well as social and economic welfare. The Centers for Disease Control and Prevention ("CDC") estimates that the total "economic burden" of prescription opioid misuse alone in the United States is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.[14]

45. Recently, the congressionally-chartered National Safety Council revealed that, for the first time in U.S. history, a person is more likely to die from an accidental opioid overdose than from a motor vehicle crash. The analysis showed that the odds of dying from opioid overdose are also higher than from falls, drowning, gun assault, or choking.[15]

46. According to the CDC, retail opioid prescriptions were dispensed in 2017 at a national rate of 58.7 prescriptions per 100 persons.[16]

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[13] U.S. Ctrs. for Disease Control & Prevention, National Center for Health Statistics, *National Vital Statistics System, Mortality*, CDC WONDER (2018), https://wonder.cdc.gov.

[14] Florence CS, Zhou C, Luo F, Xu L., The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 54 Med Care. 901-906 (2016).

[15] Nat'l Safety Council, *Injury Facts*, https://injuryfacts.nsc.org/all-injuries/preventable-death-overview/odds-of-dying/; *see also* Press Release, Nat'l Safety Council, *For the First Time, We're More Likely to Die from Accidental Opioid Overdose than Motor Vehicle Crash* (Jan. 14, 2019), https://www.nsc.org/in-the-newsroom/for-the-first-time-were-more-likely-to-die-from-accidental-opioid-overdose-than-motor-vehicle-crash).

[16] U.S. Ctrs. for Disease Control & Prevention, *U.S. Opioid Prescribing Rate Maps,* https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html.

47. From 1999 to 2017, almost 400,000 people died from an overdose involving any opioid, including prescription and illicit opioids.[17] This rise in opioid overdose deaths can be outlined in three distinct waves:

- The first wave began with increased prescribing of opioids in the 1990s, with overdose deaths involving prescription opioids (natural and semi-synthetic opioids and methadone) increasing since at least 1999.
- The second wave began in 2010, with rapid increases in overdose deaths involving heroin.
- The third wave began in 2013, with significant increases in overdose deaths involving synthetic opioids – particularly those involving fentanyl.[18]

48. Neonatal Abstinence Syndrome ("NAS") or neonatal opioid withdrawal syndrome ("NOWS") may occur when a woman uses drugs such as opioids during pregnancy. A recent national study showed a fivefold increase in the incidence of NAS/NOWS between 2004 and 2014, from 1.5 cases per 1,000 hospital births to 8.0 cases per 1,000 hospital births. That is one baby born with NAS/NOWS every 15 minutes in the United States. During the same period, hospital costs for NAS/NOWS births increased from $91 million to $563 million, after adjusting for inflation.[19]

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[17] Scholl L., Seth P., Kariisa M., Wilson N., Baldwin G., *Drug and Opioid-Involved Overdose Deaths – United States, 2013-2017*. Morb. And Mortal. Wkly Rep. (Jan. 4, 2019), https://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm.

[18] *Id.; see also* Rudd R.A., Aleshire N., Zibbell J.E., Gladden R.M. *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*, 64 Morb. And Mortal Wkly. Rep. 1378-82 (2016).

[19] NIH National Institute on Drug Abuse, *Advancing Addiction Science*, https://www.drugabuse.gov/drugs-abuse/opioids#summary-of-the-issue; NIH National Institute on Drug Abuse, *Advancing Addiction Science, Tennessee Opioid Summary, Opioid-Involved Overdose Deaths*, https://www.drugabuse.gov/opioid-summaries-by-state/tennessee-opioid-summary.

A. The Impact on Georgia

49. Georgia finds itself in the midst of an unprecedented prescription drug crisis, with hundreds of deaths attributable to opioid prescription drug overdoses every year.[20]

50. The State of Georgia had the eleventh highest number of opioid overdoses in the United States between 1999 and 2014.[21] Opioid-involved overdose deaths have not just increased – *but exploded by an astonishing 1000%* -- since 1999 when these drugs were first meaningfully introduced to the State of Georgia.[22]

51. Statistics in recent years show the ever-increasing momentum of this crisis: from 2010 to 2017, the total number of documented, opioid-involved overdose deaths in Georgia increased by an astounding 104%, from 514 to 1051 deaths.[23] In 2017, opioid-involved overdoses accounted for 5,656 emergency department visits and 2,622 hospitalizations. Tellingly, the annual number of such hospital admissions had tripled since 2000.[24] In 2018, there were 1,396 deaths attributed to all drugs in the State of Georgia, but an overwhelming number of them (1,051) were the result of opioids.[25]

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[20]The Henry J. Kaiser Family Foundation, *Opioid Overdose Deaths and Opioid Overdose Deaths as a Percent of All Drug Overdose Deaths* (2015), https://www.kff.org/other/state-indicator/opioid-overdose-deaths/.

[21] Substance Abuse Research Alliance, *Prescription Opioids and Heroin Epidemic in Georgia, 2017*, http://www.senate.ga.gov/sro/Documents/StudyCommRpts/OpioidsAppendix.pdf.

[22] Online Analytical Statistical Information System (OASIS) Trending Tool – Drug Overdoses Statistics, https://oasis.state.ga.us/.

[23] Georgia Department of Public Health, *Opioid Overdose Surveillance Georgia, 2017*, https://dph.georgia.gov/sites/dph.georgia.gov/files/2017%20Georgia%20Opioid%20Overdose%20Report%20Final.pdf.

[24] Online Analytical Statistical Information System (OASIS) Trending Tool – Drug Overdoses Statistics, https://oasis.state.ga.us/.

[25] Online Analytical Statistical Information System (OASIS) Trending Tool – Drug Overdoses Statistics, https://oasis.state.ga.us/.

52. The death, addiction, and increased cost associated with prescription opioids is a direct consequence of Georgia's opioid prescription rate increase over the same time period. By 2013, Georgia's average prescription rate for opioids (90.7 per 100 persons) was well over the national average (79.3).[26] In 2016, there were 0.778 opioid prescriptions per person in Georgia, according to the CDC.[27]

B. The Impact on Kentucky

53. The Commonwealth of Kentucky has been hit especially hard by the opioid epidemic, ranking fifth in the nation for opioid-related deaths in 2015. In 2015, 102 opioid prescriptions were written for every 100 Kentucky residents, 1.5 times the national average. In 2016 alone, there were 1,404 reported fatal drug overdoses in Kentucky—117 per month. Fentanyl was involved in 623—approximately 47%—of those deaths. In 2017, there were 1,565 fatal drug overdoses in Kentucky, which increased the average death rate to approximately 130 deaths per month.

54. In addition to opioid-related fatalities, the Commonwealth has suffered other serious injuries. Kentucky has seen a dramatic increase in opioid addiction, reflected, in part, in the increase in Medicaid spending for medications to treat such addiction, which doubled in just two years—from $56 million in 2014 to $117 million in 2016.

55. Children are especially vulnerable to the opioid epidemic. In just one 12-month period, between August 1, 2014 and July 31, 2015, 1,234 infants in Kentucky were born addicted to opioids, more than 100 newborns per month. Many of these infants must be treated in neonatal

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[26] Ctrs. for Disease Control & Prevention, *U.S. State Prescribing Rates, 2016*, https://www.cdc.gov/drugoverdose/maps/rxstate2016.html.

[27] *Id.*

intensive care units while they painfully withdraw from the drugs. Children also suffer when removed from their homes due to their parents' opioid abuse and addiction.

56. Kentucky has had one of the highest rates of pregnant women using opioids in the country. In 2014, the Commonwealth had the third-highest rate of pregnant women with opioid use disorder. In 2017, the number of babies born with NAS in the Commonwealth had increased by 375% since 2007.

C. The Impact on Tennessee

57. In 2017, there were 644 deaths in Tennessee from prescription opioid overdoses. And the majority of these individuals (58%) filled a prescription for a controlled substance within 60 days of their deaths.

58. The abuse and diversion of prescription drugs, along with the associated morbidity and mortality, has been identified as one of the most serious and costly issues facing Tennesseans today. Tennessee, located in the mid-south and bordered by eight states, is geographically and culturally situated in the middle of the national prescription drug overdose epidemic. In 2015, Tennessee had the tenth highest drug overdose mortality rate in the US, most of which was due to prescription drugs. Opioid use is disproportionately high in the northeastern (Appalachian) region of the state, while heroin use is highest in the southwestern (Memphis) area, reflecting disparities for both geographic and racial/ethnic segments of the population.

59. In 2017, Tennessee providers wrote 94.4 opioid prescriptions for every 100 persons. This was the third highest prescribing rate in the country and 1.5 times greater than the average U.S. rate of 58.7 prescriptions.

60. The greatest increase in opioid deaths was seen in cases involving synthetic opioids (mainly fentanyl): a rise from 77 deaths in 2012 to 590 in 2017.

61. The Tennessee Department of Health (TDH) requires that all cases of NAS/NOWS be reported within 30 days of diagnosis. In 2017, there were 1,090 cases of NAS/NOWS reported, representing 1.35% of all live births, and a 16 percent increase from 936 cases in 2013. Of the cases reported in the state in 2017, nearly 1 in 3 occurred as a result of exposure to diverted prescription opioid medications.

D. The Impact on Virginia

62. Between 2007 and 2019, 5,410 Virginians have fatally overdosed on prescription opioids.[28] In 2017, 507 deaths in Virginia were attributable to prescription opioids (excluding fentanyl), more than in any other year.[29]

63. Even when opioid users do not die from an overdose, they may require significant medical intervention and incur health care costs. One such cost is the immediate administration of Narcan (a brand of naloxone), which counteracts the effects of an overdose. Virginia reported 4,076 administrations of Narcan in 2016.[30]

64. Southwest Virginia (where Food City is headquartered) has been particularly hard hit. Local law enforcement officials have reported how prescription drug abuse and diversion has been a huge problem in the region. According to Wise County Commonwealth's Attorney Ron Elkins, prescription abuse in his county was "a massive problem. We have one of the busiest – if not the most busy – drug task forces in Virginia and the majority of the work they do deals with

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[28] Va. Dep't of Health, Number and Rate of All Fatal Prescription Opioid (Excluding Fentanyl) Overdoses by Locality of Injury and Year of Death, 2007-2019, http://www.vdh.virginia.gov/content/uploads/sites/18/2019/07/Prescription-Opioids-Ex-Fentanyl.xlsx.

[29] *Id.*

[30] Va. Dep't of Health, *Virginia Opioid Addiction Indicators*, http://www.vdh.virginia.gov/data/opioid-overdose/

prescription drugs."[31] Elkins said between 60 percent and 70 percent of his office's caseload deals with prescription drugs, which he said is one of the biggest percentages in the state.[32]

65. According to Chris Gilley, a special agent with the Virginia State Police, prescription drugs were "the lion's share" of drugs with which the Southwest Virginia Regional Drug Task Force, based in Big Stone Gap, dealt. "In the past four or five years, 75 to 85 percent of the investigations we handle deal with the distribution of pharmaceutical drugs," he said. "The past decade has been a decade of pharmaceutical drugs."[33]

V. THE APPLICABLE STATUTES

66. In March 2016, the CDC, in order to reduce opioid addiction, overdoses, and deaths, published specific recommendations for clinicians who prescribe opioids outside of cancer treatment, palliative care, and end-of-life care.[34] The CDC recommendations are based on "[s]cientific research [that] has identified high-risk prescribing practices that have contributed to the overdose epidemic (*e.g.*, high-dose prescribing, overlapping opioid and benzodiazepine prescriptions, and extended-release/long-acting opioids for acute pain)."[35]

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[31] Allie Robinson, *Medicine Abuse Project kicks off this week*, Herald Courier, https://heraldcourier.com/news/medicine-abuse-project-kicks-off-this-week/article_d6edfee8-52b6-5538-a2c1-dddd66d779a7.html.

[32] *Id.*

[33] *Id.*

[34] *See generally* Deborah Dowell, M.D. *et al.*, *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, 65 Morb. And Mort. Wkly. Rep. 1 (2016) [hereinafter, *CDC Guideline*].

[35] *Id.* at 3.

67. Congress has found that pharmacies are partly responsible for the crisis: "The opioid epidemic ... has arisen, in part, from the diversion of prescription opioids through illegal dispensing practices at pharmacies."[36]

68. The grave statistics about the human toll of the opioid crisis are shocking enough. But the crisis goes beyond the human toll. Not only have millions of lives been lost to opioid addiction, millions of Government Program dollars have been squandered on inappropriate and/or otherwise medically unnecessary opioid prescriptions.

69. Food City has put profits over patients and indiscriminately dispensed and billed opioid prescriptions that were inappropriate and/or medically unnecessary.

70. Food City knowingly violated its duties under the CSA and Georgia, Kentucky, Tennessee, and Virginia state pharmacy laws and regulations, ignoring obviously medically unnecessary prescriptions, filling them, and fraudulently charging Government Programs.

A. The Controlled Substances Act

71. The Controlled Substances Act ("CSA") and its implementing regulations govern the manufacture, distribution, and dispensation of controlled substances in the United States. From the outset, Congress recognized the importance of preventing the diversion of drugs from legitimate to illegitimate uses. The CSA accordingly establishes a closed regulatory system under which it is unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.[37]

72. The CSA categorizes controlled substances in five "Schedules."

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[36] U.S. Senate Homeland Sec. & Governmental Aff. Comm., Ranking Member's Off., *Fueling an Epidemic: A Flood of 1.6 Billion Doses of Opioids into Missouri and the Need for Stronger DEA Enforcement* 4 (July 12, 2017).

[37] *See* 21 U.S.C. § 841(a).

73. Schedule II (also called herein CII) contains drugs with "a high potential for abuse" that "may lead to severe psychological or physical dependence," but nonetheless have "a currently accepted medical use in treatment."[38]

74. Schedule III contains drugs in which, although the abuse potential is less than a Schedule II drug, such abuse may lead to moderate "physical dependence or high psychological dependence." Schedule III drugs also have "a currently accepted medical use."[39]

75. Schedule IV contains drugs that, although having a lower abuse potential than Schedule III drugs, still may lead to a physical or psychological dependence when abused.[40]

76. Schedule V contains drugs that, although having a lower abuse potential than Schedule IV drugs, still may lead to a physical or psychological dependence when abused.[41]

77. The CSA makes it "unlawful for any person knowingly or intentionally to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance" except as specifically authorized.[42]

78. Accordingly, the CSA requires those who manufacture, distribute, or dispense controlled substances to obtain a registration from the DEA.[43] A registrant is only permitted to dispense or distribute controlled substances "to the extent authorized by their registration and in conformity with the [CSA]."[44]

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[38] 21 U.S.C. § 812(b)(2).

[39] 21 U.S.C. § 812(b)(3).

[40] 21 U.S.C. § 812(b)(4).

[41] 21 U.S.C. § 812(b)(5).

[42] 21 U.S.C. § 841(a)(1).

[43] 21 U.S.C. § 822(a).

[44] 21 U.S.C. § 822(b).

79. A pharmacy also needs to know there is a corresponding responsibility for the pharmacist who fills the prescription.[45] An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription within the meaning and intent of the CSA.[46] The pharmacy knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

80. A pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription. Such a determination is made before the prescription is dispensed. The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances. Such action is a felony offense, which may result in the loss of one's business or professional license.[47]

81. At all times relevant to this Complaint, Food City had registered its retail pharmacies with the DEA in Schedule II–V controlled substances. Those DEA registrations authorize Food City pharmacies to "dispense" controlled substances, which "means to deliver a controlled substance to an ultimate user … by, or pursuant to the lawful order of, a practitioner."[48]

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[45] United States Department of Justice, Drug Enforcement Administration Office of Diversion Control, *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act*, 29 (Rev. 2010).

[46] 21 U.S.C. § 829.

[47] *See, e.g., U.S. v. Kershman*, 555 F.2d 198 (8th Cir. 1977).

[48] 21 U.S.C. §§ 823(f), 802(10).

82. Agents and employees of a registered manufacturer, distributor, or dispenser of controlled substances, such as a pharmacist employed by a registered pharmacy like Food City, are not required to register with the DEA "if such agent or employee is acting in the usual course of his business or employment."[49]

83. Under the CSA, the lawful dispensing of controlled substances is governed by 28 U.S.C. § 829 and more specifically in Part 1306 of the CSA's implementing regulations.[50]

84. Unless dispensed directly by a non-pharmacist practitioner, no Schedule II controlled substance may be dispensed without the written prescription of a practitioner, such as a physician, except in an emergency.[51] Similarly, unless directly dispensed, no Schedule III or IV controlled substance may be dispensed without a written or oral prescription from a practitioner.[52]

85. Such a prescription for a controlled substance may only be issued by an individual who is (a) "authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession" and (b) registered with the DEA.[53]

86. A prescription, whether written or oral, is legally valid under the CSA **only** if it is issued for "a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."[54] Moreover, "[a]n order purporting to be a prescription issued not in the usual course of professional treatment … is not a prescription within the meaning and intent of [21 U.S.C. § 829] and **the person knowingly filling such a purported prescription**, as well as the

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[49] 21 U.S.C. § 822(c)(1).

[50] *See generally* 21 C.F.R. § 1306.

[51] 21 U.S.C. § 829(a).

[52] 21 U.S.C. § 829(b).

[53] 21 U.S.C. § 822; 21 C.F.R. § 1306.03.

[54] 21 C.F.R. § 1306.04(a).

person issuing it, **shall be subject to the penalties** provided for violations of the provisions of law relating to controlled substances."[55] (emphasis added)

87. As a result, the "responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription."[56] Thus, a pharmacist may not fill a controlled substance prescription unless it has been issued for a legitimate medical purpose.

88. Moreover, "[a] prescription for a controlled substance may *only* be filled by a pharmacist, *acting in the usual course of his professional practice* and either registered individually, or employed in a registered pharmacy...."[57] (emphasis added)

89. Pharmacists are therefore permitted to dispense a controlled substance in any given instance if, *but only if*, such dispensing would be in accordance with a generally accepted, objective standard of practice – *i.e.,* "the usual course of his [or her] professional practice" of pharmacy.[58]

90. Consequently, a pharmacist is required to refuse to fill a prescription if he or she knows or has reason to know that the prescription was not written for a legitimate medical purpose.[59]

91. This requires a pharmacist to use sound professional judgment in determining the legitimacy of a controlled substance prescription, which includes paying attention to the number of prescriptions issued, the number of dosage units prescribed, the doctor writing the prescriptions, and whether the drugs prescribed have a high rate of abuse or diversion. The pharmacist has a legal duty to recognize "red flags" or warning signs that raise (or should raise) a reasonable suspicion

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[55] *Id.* (emphasis added).

[56] *Id.*

[57] 21 C.F.R. § 1306.06 (emphasis added).

[58] *Id.*

[59] *See* 21 C.F.R. §§ 1306.04, 1306.06.

that a prescription for a controlled substance is not legitimate. The existence of such indicia obligates the pharmacist to conduct a sufficient investigation to determine that the prescription is actually legitimate before dispensing.

1. *Pharmacies Are Obligated Not to Fill Prescriptions Until Red Flags Are Resolved*

92. A pharmacy cannot ignore red flags indicative of diversion. On the contrary, "a pharmacist is obligated to refuse to fill a prescription if he knows or has reason to know that the prescription was not written for a legitimate medical purpose."[60] "[W]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid actual knowledge of the real purpose of the prescriptions."[61] Thus, § 1306.064 requires "pharmacists [to] use common sense and professional judgment," which includes paying attention to the "number of prescriptions issued, the number of dosage units prescribed, the duration and pattern of the alleged treatment," the number of doctors writing prescriptions and whether the drugs prescribed have a high rate of abuse or diversion.[62] "When [pharmacists']

[60] *Medic-Aid Pharmacy*, 55 Fed. Reg. 30,043, 30,044, 1990 WL 328750 (Dep't of Justice July 24, 1990).

[61] *East Main Street Pharmacy*, Affirmance of Suspension Order, 75 Fed. Reg. 66149-01, 2010 WL 4218766 (Dep't of Justice Oct. 27, 2010).

[62] *Ralph J. Bertolino Pharmacy, Inc.*, 55 Fed. Reg. 4,729, 4,730, 1990 WL 352775 (Dep't of Justice Feb. 9, 1990).

suspicions are aroused as reasonable professionals," they must at least verify the prescription's propriety, and if not satisfied by the answer they must "refuse to dispense."[63]

93. Courts, too, have recognized the obligation *not* to dispense until red flags are resolved.[64] In *Medicine Shoppe-Jonesborough,* the Sixth Circuit affirmed a pharmacy's liability for filling false or fraudulent prescriptions for controlled substances, concluding that the pharmacy violated § 829 of the CSA and 21 C.F.R. § 1306.04. The Court held that "[t]he CSA forbids a pharmacy to dispense a Schedule II, III, or IV controlled substance without a prescription, 21 U.S.C. § 829(a)-(b), which 'must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice,' 21 C.F.R. § 1306.04(a)."[65] Prescriptions that "involved excessive" quantities of drugs and "remedies outside the prescriber's ordinary area of practice" "should have raised red flags at Medicine Shoppe."[66] "[B]y filling these prescriptions anyway. . . the pharmacy not only violated its duties under federal (and state) law to ensure that only proper prescriptions were filled but also put public health and safety at risk."[67]

94. The Court presiding over the federal multi-district litigation involving claims against opioid manufactures, distributors, and dispensers (hereinafter "Opioids MDL") recently

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[63] *Id.*; *see also Townwood Pharmacy*; 63 Fed Reg. 8,477, 1998 WL 64863 (Dep't of Justice Feb. 19, 1998) (revocation of registration); *Grider Drug 1 & Grider Drug 2*, 77 Fed. Reg. 44070-01, 2012 WL 3027634 (Dep't of Justice July 26, 2012) (decision and order); *The Medicine Dropper*; 76 Fed. Reg. 20,039, 2011 WL 1343276 (Dep't of Justice April 11, 2011) (revocation of registration); *Medicine Shoppe-Jonesborough*, 73 Fed. Reg. 364-01, 2008 WL 34619 (Dep't of Justice Jan. 2, 2008) (revocation of registration); *Notice of United Prescriptions Services, Inc.*, 72 Fed. Reg. 50397- 01, 50407-8, 2007 WL 2455578 (Aug. 31, 2007) (revocation of registration).

[64] *See Medicine Shoppe-Jonesborough v. Drug Enforcement Administration*, 300 F. App'x 409 (6th Cir. 2008); United States v. Henry, 727 F.2d 1373, 1378-79 (5th Cir.1984); Holiday CVS, L.L.C. v. Holder, 839 F. Supp.2d 145 (D.D.C. 2012).

[65] *Id.* at 412 (emphasis added).

[66] *Id.*

[67] *Id.*

addressed this very issue. The Court unequivocally stated that "[t]here is no question that dispensers of controlled substances are obligated to check for and conclusively resolve red flags of possible diversion prior to dispensing those substances."[68]

95. In fact, the Opioids MDL Court found that the corporate parents of chain pharmacies have an affirmative obligation under the CSA to "design and implement systems, policies, or procedures to identify red flag prescriptions."[69] The Court reasoned that chain pharmacies " cannot collect data as required by the statute, employ a licensed pharmacist as required by the statute, identify red flags as required by Agency decisions, but then do nothing with their collected data and leave their pharmacist-employees with the sole responsibility to ensure only proper prescriptions are filled. Possessing, yet doing nothing with, information about possible diversion would actually ***facilitate*** diversion, and thus violate the CSA's fundamental mandate that '**[a]ll applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.**'" 21 C.F.R. § 1301.71(a) (emphasis added)."[70]

2. *The Corporate Parent of Chain Pharmacies Is Responsible for the Dispensing Practices in Its Stores*

96. The responsibility for dispensing is not limited to pharmacists, pharmacies, or holders of DEA dispensing registrations. Rather, the corporate parent of a pharmacy may be

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[68] *In Re: National Prescription Opiate Litigation,* Opinion and Order (Case No. 17-md-2804) (Dkt. 3403) at 22.

[69] *Id.* at 25.

[70] *Id.*

responsible for the dispensing practices of its pharmacies and pharmacists.[71] This is so regardless of whether the parent is a registrant under the CSA or whether the parent is the entity or person actually doing the dispensing.

97. In short, case law discussed below holds that individuals or entities who have the ultimate responsibility for the dispensing of controlled substances can be liable for violations of the CSA, regardless of whether they are DEA registrants. To the extent that a corporate parent of a chain pharmacy defendant exerts sufficient control over the pharmacy operations at its stores, which the large chains likely do, these corporate parents can be held liable for dispensing violations. Moreover, to the extent that the chain pharmacy defendants attempt to blame the individual pharmacists themselves, cases hold that parent company liability can be imposed in addition to any individual pharmacist's liability.

98. Courts routinely find that liability can attach to a broad array of persons or entities under Section 842. In particular, courts reject two arguments for limiting liability under Section 842 and its regulations. First, courts find that Section 842 can impose liability on non-registrants. Second, courts find that Section 1306.4 can be the basis for liability of pharmacy owners in addition the pharmacists themselves. These holdings are based on the purpose and structure of the CSA: those who have the ultimate responsibility for the controlled substances and ensuring compliance with the CSA should be held liable for violations, regardless of whether they are registered with the DEA.

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[71] *See United States v. City Pharmacy, LLC*, No. 3:16-CV-24, 2016 WL 9045859, (N.D. W.Va. Dec. 19, 2016); *United States v. Stidham*, 938 F. Supp. 808, 814 (S.D.Ala.1996); *United States v. Poulin*, 926 F. Supp. 246, 250, 253 (D. Mass.1996); *United States v. Robinson,* No. 12-20319-CIV, 2012 WL 3984786, at *6 (S.D. Fla. Sept. 11, 2012).

99. The Court in the Opioids MDL firmly rejected many of the arguments against holding corporate parents of chain pharmacies responsible for the dispensing at individual stores.[72]

3. *The CSA Applies to All Persons Who Dispense Controlled Substances*

100. Courts have found that because the plain language of Section 842 extends its requirements to "all persons," registrants and non-registrants alike are responsible for complying with the law.[73] Importantly, in those cases, the courts found that because the pharmacy owners, who were not registrants, essentially operated the facilities on a day-to-day basis, they were not exempted from the requirements of Section 842.[74]

101. At least one court has explicitly held that a non-registrant pharmacy owner can be held liable for dispensing controlled substances without valid prescriptions. In *USA v. City Pharmacy*, the court found that the owner of the pharmacy could be held liable in his personal capacity for violations of Section 842(a)(1) even though he was not a registrant and the pharmacies he owned were separately incorporated.[75] The United States brought an action alleging that City

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[72] *See generally In Re: National Prescription Opiate Litigation*, Opinion and Order (Case No. 17-md-2804) (Dkt. 3403)

[73] *See United States v. Blanton*, 730 F.2d 1425, 1434 (11th Cir. 1984) (Section 842(a)(5) applied to a physician who was not properly registered with the DEA); *United States v. Clinical Leasing Serv., Inc.*, 759 F. Supp. 310, 313–14 (E.D. La. 1990), *aff'd*, 925 F.2d 120 (5th Cir. 1991) ("Had Congress intended to limit the applicability of § 842(a)(5) to registrants only, it would have done so"); *United States v. Stidham*, 938 F. Supp. 808, 814 (S.D. Ala. 1996); *United States v. Poulin*, 926 F. Supp. 246, 250, 253 (D. Mass. 1996).

[74] *Stidman*, 938 F. Supp. at 809, 814 (the owner of a clinic, who was not a registrant, could be liable because he "shouldered [the] responsibility [to provide a system for the control of drug traffic and to prevent the abuse of drugs] and derived the benefits and profits from operating a methadone clinic."); *Poulin*, 926 F. Supp. at 249, 253 ("Although Mattapoisett Pharmacy, Inc. was listed as the registrant, the statute specifically makes the stated obligations to produce required records applicable to all persons, not simply to registrants.").

[75] *United States v. City Pharmacy, LLC*, No. 3:16-CV-24, 2016 WL 9045859, (N.D. W.Va. Dec. 19, 2016).

Pharmacy LLC and City Pharmacy of Charles Town, Inc. violated Section 842(a)(1) by filling illegitimate prescriptions for controlled substances that raised one or more red flags, such as customers traveling long distances or customer receiving drug cocktails.[76]

102. The Court held that Section "842(a)(1) applies to non-registrants."[77] The Court continued, explaining that "because part C of the CSA applies broadly to all persons involved in the manufacture, distribution, and dispensing of controlled substances, including lay-persons, defendant Lewis may potentially be held liable for his conduct."[78] To support its conclusion, the Court concentrated on Defendant Lewis' involvement with the pharmacies at issue, looking specifically at his investment of the funds to organize and open the pharmacy, the active role he played in the management of the pharmacies, including overseeing the finances of the pharmacies, managing personnel, and delivering prescriptions to customers.

103. The *City Pharmacy* Court also found that the individual defendant could not use the pharmacies' separate incorporation to shield himself from CSA liability. Evaluating various legal mechanisms for piercing the corporate form, the court concluded that the pharmacies "were being used to evade the legal requirements within and undermine the public policy foundations of the CSA."[79] Thus, the Court held, "given the nature of these criminally-grounded allegations, it is not a defense to liability in this case for defendant Lewis to assert that he is shielded by the

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[76] *Id.* at *2.

[77] *Id.* at *2 (citing *United States v. Moore*, 423 U.S. 122, 134 n.11 (1975) and *United States v. Stidham*, 938 F. Supp. 808, 813-814 (S.D. Ala. 1996)).

[78] *Id.*

[79] *Id.* at *4.

corporate form. [The pharmacies] were allegedly the entities used to evade and subvert the requirements of the CSA."[80]

104. Just like the defendant in *City Pharmacy*, Food City invests the funds to organize and open its numerous pharmacies and plays a very active role in the management of its pharmacies including overseeing the finances of the pharmacies, managing personnel, and delivering prescriptions to customers.

[80] *Id.*; *see also Poulin*, 926 F. Supp. at 249 *("*"Mattapoisett Pharmacy, Inc. is also the alter ego of its sole owner, David Poulin, and thus David Poulin cannot use the corporate name to shield himself from personal liability."); *S & S Pharmacy*; 46 Fed. Reg. 13051-52 (Dep't of Justice Feb. 19, 1981) ("[T]he Administrator has in the past looked behind the corporate-veil to revoke or deny a registration when a responsible official of a corporate registrant has been convicted of violating the laws relating to controlled substances."); *United States v. Robinson*, No. 12-20319-CIV, 2012 WL 3984786, (S.D. Fla. Sept. 11, 2012), (finding a non-registrant owner of a pharmacy could be held liable for violations of Section 842 because the defendant was "alleged to have had responsibility over the controlled substances" and holding that "[w]here corporate officers have been in a position to prevent or correct the violations at issue, courts have found that there is individual liability under the [Section 842], which plainly applies to all 'persons.'"); *United States v. Ahmad*, No. 4:15CV-181-JM, 2016 WL 11645908, at *3 (E.D. Ark. May 2, 2016), *aff'd sub nom. United States v. United Pain Care, Ltd.*, 747 F. App'x 439 (8th Cir. 2019) (an owner receiving the "benefits and profit" of a pharmacy, but who was not a registrant or a medical professional, can be liable for violations of the CSA because he was still "responsible for making sure that [CSA] requirements were met.").

4. *Food City Cannot Escape Liability for Its Corporate Malfeasance by Blaming Its Pharmacists*

105. In addition to finding that individuals or entities who own and control pharmacies can be liable for CSA violations, irrespective of their DEA registration status, the case law also makes it clear that pharmacies cannot escape liability under the CSA by simply blaming the pharmacists who work for them. Even though the "corresponding responsibility" of pharmacists is discussed in terms of what a pharmacist – not a pharmacy – must do, courts have found that a narrow reading of the language to insulate pharmacies from liability is not supported by the language or structure of the regulations. In fact, one Court has called such a reading "deeply troubling."[81]

106. In *United States v. Appalachian Reg'l Healthcare, Inc.*, 246 F. Supp. 3d 1184, 1186 (E.D. Ky. 2017), the Court looked at the regulations regarding dispensing under Section 842 and found that the pharmacy owner could be held personally liable for dispensing violations.

107. Defendant Appalachian Regional Healthcare ("ARH") unsuccessfully argued that it could not be held liable as a corporate pharmacy under Section 842(a)(1) because its implementing regulations, namely 21 C.F.R. § 1306.04, articulated the duties under that section in terms of the "pharmacist" or "practitioner," not the corporate pharmacy entity.[82] The court rejected ARH's narrow, technical reading, instead holding that "when § 1306.04(a) states that the person knowingly filling the prescription is subject to penalties, it contemplates liability for corporate

[81] *In Re: National Prescription Opiate Litigation,* Opinion and Order (Case No. 17-md-2804) (Dkt. 3403) at 13.

[82] *See, e.g,* § 1306.4(a) ("The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.").

entities as well."[83] The court continued, finding that there is "nothing inconsistent about articulating the responsibilities of individual practitioners and pharmacists while simultaneously indicating that other entities may be subject to penalties for their role in issuing and filling invalid prescriptions."[84]

108. Likewise, other federal courts have found pharmacies and other DEA registrants liable for violations of the CSA and CSA Regulations.[85] For example, in *Medicine Shoppe-Jonesborough v. Drug Enforcement Administration*, 300 F. App'x 409 (6th Cir. 2008), the Sixth Circuit affirmed a pharmacy's liability for filling false or fraudulent prescriptions for controlled substances, concluding that the pharmacy violated Section 829 of the CSA and Section 1306.04 of the CSA Regulations.

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[83] *United States v. Appalachian Reg'l Healthcare, Inc.*, 246 F. Supp. 3d at 1189.

[84] *Id.* at 1189-1190; *see also Moore v. Covenant Care Ohio, Inc.*, 18 N.E.3d 1260, 1270 (Oh. App. 2014) (a corporate pharmacy whose subsidiary voluntarily undertook to provide pharmaceutical services to a nursing home owed a duty to exercise reasonable care in providing such services and also owed a common law duty to exercise reasonable care in dispensing and labeling of medicines).

[85] *See United States v. Green Drugs*, 905 F.2d 694, 694-5 (3rd Cir. 1990) (affirming retail pharmacy liability for violating Section 842(a)); *United States v. Clinical Leasing Serv., Inc.*, 925 F.2d 120, 122-3 (5th Cir. 1991) (affirming liability under Section 842(a) for corporate operator of clinic that illegally distributed controlled substances); *United States v. Cap Quality Care, Inc.*, 486 F. Supp. 2d 47, 54 (D. Maine 2007) (granting summary judgment to the United States on claims that DEA registrant clinic improperly dispensed controlled substances in violation of Sections 829 and 842); *United States v. Grab Bag Distrib.*, 189 F. Supp. 2d 1072, 1082 (E.D. Cal. 2002) (granting summary judgment to the United States on liability); *United States v. Little*, 59 F. Supp. 2d 177, 186-8 (D. Mass. 1999) (granting summary judgment to Government for pharmacy's violations of § 842(a) and concluding "a pharmacy empowered to dispense controlled substances will now be held liable . . . if it knew or should have known about an illegal diversion, or inaccurate records, and chose to do nothing"); *Poulin*, 926 F. Supp. at 252-3 (holding pharmacy liable for "filling a total of six invalid prescriptions"); *United States v. Queen Village Pharm.*, No. 89-2778, 1990 WL 165907, *2-4 (E.D. Pa. Oct. 25, 1990) (finding retail pharmacy liable for violating Section 842(a)).

109. Specifically, the Court held that "[t]he CSA forbids a pharmacy to dispense a Schedule II, III, or IV controlled substance without a prescription, 21 U.S.C. § 829(a)-(b), which 'must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice,' 21 C.F.R. § 1306.04(a)."[86] "Medicine Shoppe fell asleep at the wheel in honoring prescriptions no reasonable pharmacist would fill without further inquiry."[87] Prescriptions that "involved excessive" quantities of drugs and "remedies outside the prescriber's ordinary area of practice" "should have raised red flags at Medicine Shoppe."[88] "[B]y filling these prescriptions anyway . . . the pharmacy not only violated its duties under federal (and state) law to ensure that only proper prescriptions were filled but also put public health and safety at risk."[89] The Sixth Circuit made no distinction between the pharmacy and the pharmacists employed there when determining liability.[90]

110. The Opioids MDL also "firmly rejected" the argument that only individual pharmacists could be held liable for illegal dispensing: "The Court concludes that the Pharmacy Defendants have not shown that the sole responsibility for their dispensing practices rests with their pharmacist-employees. Rather, the CSA makes clear that any *person*, which includes the

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[86] *Id.* at 412 (emphasis added).

[87] *Id.* at 413.

[88] *Id.*

[89] *Id.*

[90] *See also Jones Total Health Care Pharmacy LLC and SND Health Care LLC v. Drug Enforcement Administration*, 881 F.3d 823, 835 (11th Cir. 2018) (affirming revocation of pharmacy registration for, among other things, pharmacists dispensing prescriptions that prescriptions presented various red flags, *i.e.*, indicia that the prescriptions were not issued for a legitimate medical purpose without resolving red flags).

pharmacy itself, who knowingly fills or allows to be an illegitimate prescription is in violation of the [Controlled Substances] Act."[91]

111. These decisions make clear that the dispensing obligations under the CSA are not imposed solely on pharmacists, but on pharmacies and their corporate owners. For this reason, the chain pharmacy parent corporations like Food City had a responsibility, under the CSA, not to dispense opioids in the face of unresolved red flags about the legitimacy of the prescriptions.

5. *The Purpose and Intent of the CSA Bolsters Finding Liability of Corporate Parent Food City*

112. The logic of the above authority is consistent with the purpose and intent of the CSA. The Supreme Court has explained that with the CSA "Congress was particularly concerned with the diversion of drugs from legitimate channels to illegitimate channels."[92] So, to address this concern, courts do not want defendants using the DEA registration process and requirements (*i.e.*, the structure of the legitimate channels) to shield those responsible from liability. As one court put it, "[t]o accept [defendant's] argument that the Act does not apply to her [because she was not a registrant], even though she was responsible for the drugs, would eviscerate the goal of ensuring the movement of drugs is closely controlled."[93] "The legislative history [of the CSA] indicates that Congress was concerned with the nature of the drug transaction, rather than with the status of the defendant."[94]

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[91] *In Re: National Prescription Opiate Litigation,* Opinion and Order (Case No. 17-md-2804) (Dkt. 3403) at 21.

[92] *United States v. Moore*, 423 U.S. 122, 135 (1975).

[93] *Robinson,* 2012 WL 3984786 at *7.

[94] *United States v. Moore*, 423 U.S. at 134.

113. The DEA made a similar finding in *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195 Decision and Order.*[95] The Administrative Law Judge rejected CVS's argument that the corporate parent of a chain pharmacy was not responsible for the actions of its pharmacies. In its analysis of whether or not CVS took responsibility for its actions, the ALJ held that:

> [T]he Agency's rule is clear and the fact that CVS is a large corporation provides no reason to excuse it from explicitly acknowledging the misconduct of Respondents and their pharmacists. Therefore, I decline to create one rule for chain pharmacies and another rule for closely held or sole proprietor owned pharmacies. Because Respondents have failed to satisfy this requirement, the ALJ properly held that they have not accepted responsibility for their misconduct.[96]

114. At its most fundamental level, the purpose of the CSA and CSA regulations is to create a closed system for delivery of controlled substances and prevent the distribution of controlled substances outside of that system. To allow the entity that fully controls the operations of the registrants (such as the corporate parent of a chain pharmacy like Food City) to escape responsibility because of corporate structure thus would defeat the purpose and intent of the CSA.

115. As the Opioids MDL Court held: "[T]he Pharmacy Defendants' ultimate argument – that they cannot be liable to Plaintiffs because only their pharmacist-employees are responsible for preventing diversion of opioids via illegitimate prescriptions – is premised upon a tortured reading of the CSA and its regulations. Because Defendants' reading of the CSA is antithetical to its very purpose, the Court rejects [Pharmacy] Defendants' positions."[97]

116. Tennessee law defines the "Practice of Pharmacy" to mean a "patient-oriented health service profession in which pharmacists interact and consult with patients and other health

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[95] 77 Fed. Reg. 62316-01, 62321-2; 2012 WL 4832770 (D.E.A. Oct. 12, 2012).

[96] *Id.*

[97] *In Re: National Prescription Opiate Litigation,* Opinion and Order (Case No. 17-md-2804) (Dkt. 3403) at 25.

care professionals to enhance patients' wellness, prevent illness, and optimize outcomes."[98] That same statute further explains that the Practice of Pharmacy involves the "[t]he interpretation, evaluation and implementation of medical orders and prescription orders," and [p]articipation in drug … selection," and "[drug] evaluation, utilization or regimen review."[99]

117. The Tennessee Board of Pharmacy's Standards of Practice specifically establish that "[a] pharmacist shall be responsible for a reasonable review of a patient's record prior to dispensing each medical or prescription order. The review shall include evaluating the … order for: [o]ver-utilization or under-utilization; [t]herapeutic duplication; [d]rug-disease contraindication; [d]rug-drug interactions; [i]ncorrect drug dosage or duration of drug treatment; drug-allergy interactions; [and] clinical abuse/misuse."[100]

118. Moreover, under Tennessee law, pharmacists are required to maintain a patient profile or record system which "shall provide for the immediate retrieval of information necessary for the pharmacist to identify previous dispensed medical and prescription orders at the time a medical or prescription order is presented." With regard to the patient profile, the pharmacy must "make a reasonable effort to obtain, record, and maintain" patient information relevant to pharmacy practice including the "[p]harmacist's comments as deemed relevant."[101]

119. Consequently, the dispensing of controlled substances when faced with warning signals, without first ensuring that the prescription was issued for a legitimate purpose by a practitioner acting in the usual course of professional practice, violates both 21 U.S.C. § 842(a)

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[98] TN Code §63-10-204(39)(A).

[99] *Id.*

[100] Rules of The Tennessee Board of Pharmacy, Standards of Practice, § 1140-03.01(3)(a).

[101] *Id.* at § 1140-03.01(2)(b).

(prohibiting distributing or dispensing in violation of the prescription provisions of 21 U.S.C. § 829) because doing so violated the pharmacist's corresponding responsibility to ensure the legitimacy of the prescription (21 C.F.R. § 1306.04) and 21 U.S.C. § 841(a) (prohibiting dispensing except as authorized by the CSA) because the prescription was filled outside of the pharmacist's usual course of professional practice (21 C.F.R. § 1306.06).

120. Tennessee pharmacists have access to Controlled Substance Monitoring Program Board of Pharmacy Patient RX History Reports ("CSMD Reports"). The CSMD reports are compiled by an information system into which pharmacists in Tennessee are required to enter data regarding the controlled substance prescriptions they dispense to patients. This information system allows Tennessee pharmacists to review a patient's controlled substance prescription history before dispensing controlled substances. For example, the pharmacists can determine which doctors have prescribed controlled substances, which pharmacies have dispensed them, the quantities and dosages that have been prescribed and dispensed and when.

121. Prescribing controlled substances in amounts or for durations that are not medically necessary is beyond the scope of professional practice.

122. Prescribing controlled substances for pain will be considered to be for a legitimate medical purpose in certain narrow circumstances, including after a documented medical history, pursuant to a written treatment plan with stated objectives, and considering the risk of medication misuse or diversion.

B. The False Claims Act

123. The FCA[102] prohibits "knowingly" presenting or causing to be presented to the United States any false or fraudulent claim for payment or approval.

[102] 31 U.S.C § 3729(a)(1)(A).

124. The FCA[103] prohibits "knowingly" making, using, or causing to be used or made, a false record or statement material to a false or fraudulent claim.

125. The FCA[104] further imposes liability upon any person who conspires to commit a violation of the FCA.

126. The FCA defines a "claim" to include any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient. Any claim submitted by a Government Program provider for a payment constitutes a claim under the FCA. Any claim submitted by a provider for payment by a federal insurance plan, such as Tricare, is also a "claim" for purposes of the FCA.

127. Under the FCA, a "claim" is defined broadly to include any request or demand for money that is presented to the United States, or is made to a contractor, grantee, or other recipient, if the money is to be spent or used on the Government's behalf or to advance a Government program or interest.[105]

128. In the Medicare Part D context, the "claim" is the Prescription Drug Event (PDE) that is sent by the dispensing pharmacy to a Part D plan sponsor or Pharmacy Benefit Manager ("PBM"), and then forwarded to CMS as part of the payment process.

129. The Part D statute provides that drugs may only be reimbursed under the program if the drug is a "covered outpatient drug." Consequently, one of the elements of the PDE is to

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[103] 31 U.S.C § 3729(a)(1)(B).

[104] 31 U.S.C § 3729(a)(1)(C).

[105] 31 U.S.C. § 3729(b)(2).

designate whether a dispensed drug is a covered outpatient drug. Covered outpatient drugs must be dispensed pursuant to a valid prescription. Under the CSA and many parallel state laws, a prescription must satisfy a number of requirements. For example, the prescriber must be authorized to prescribe controlled substances in the jurisdiction in which he or she is licensed to practice, and must be either registered with DEA or exempt from registration.[106]

130. Perhaps most significantly, in order to be valid, a prescription must be issued "for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."[107] This requirement "ensures that patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse.[108] It also "bars doctors from peddling to patients who crave the drugs for those prohibited uses."[109] Violation of any one of the above requirements potentially satisfies the FCA falsity requirement.

131. The FCA provides that a person is liable to the United States Government for three times the amount of damages that the Government sustains because of the act of that person, plus a civil penalty of $5,500 to $11,000 per violation for violations that occurred before November 2, 2015 and, for violations that occurred after that date, a civil penalty of between $11,181 and $22,363.[110]

132. One method for preventing the over-prescribing of potentially harmful opioids is to pursue those who cause the submission of false or fraudulent claims for payment for those drugs under Medicare Part D, Medicaid, and other federal and state programs. The treble damages and

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[106] 21 C.F.R. § 1306.03(a).

[107] 21 C.F.R. § 1306.04(a).

[108] *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006).

[109] *Id.*

[110] 31 U.S.C. § 3729(a)(1); 28 C.F.R. § 85.5.

civil penalties awardable under the FCA, as well as State *qui tam* statutes, can provide a powerful incentive for physicians and others to avoid prescribing and dispensing these substances for indications that are not supported by the approved drug compendia.[111]

133. Relevant here, Department of Justice counsel have argued that the "combining the CSA and FCA enforcement schemes can be an effective tool to address violations of the CSA that may lead to diversion of narcotics and Part D fraud,"[112] particularly in combatting the "twin evils of opioid addiction" and Government Program fraud.[113]

C. Opioid Use and Treatment by Government Programs

134. There is an array of health care programs operated and funded by the United States and the Qui Tam States (the "Government Programs") whose purpose is to facilitate the delivery of safe and effective health care through payment or reimbursement of eligible prescription drugs for covered beneficiaries. Several of these Government Programs are described below.

135. One method for preventing the over-prescribing of potentially harmful opioids is to pursue those who cause the submission of false or fraudulent claims for payment for those drugs under Medicare Part D, Medicaid, and other federal programs. The treble damages and civil penalties awardable under the FCA can provide a powerful incentive for physicians and others to avoid prescribing and dispensing these substances for indications that are not supported by the approved drug compendia.[114]

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[111] Roger Wenthe, Fighting Opioid Abuse Under Federal Health Programs With the False Claims Act, 64 United States Attorneys' Bulletin 93, 100 (Nov. 2016).

[112] Edward A. Baker, Stacy Gerber Ward, *Pursuing False Claims Act Liability for Controlled Substances Act Violations*, 64 United States Attorneys' Bulletin 101, 113 (Nov. 2016).

[113] *Id.* at 102.

[114] Roger Wenthe, Fighting Opioid Abuse Under Federal Health Programs With the False Claims Act, 64 United States Attorneys' Bulletin 93, 100 (Nov. 2016).

1. *Medicare and Medicaid Coverage Limits for Medically Unnecessary Opioid Medications*

136. Medicare coverage for opioid medications is provided in Part D, the prescription drug benefit program available to Medicare recipients who voluntarily enroll.[115] To participate in Part D, beneficiaries must enroll in a Part D Plan of their choice. The beneficiary pays premiums to the Plan's sponsor, which is a private entity approved by the Centers for Medicare and Medicaid Services ("CMS"). Coverage in the Plan includes deductibles, copayments, and benefit caps. The beneficiary fills the prescription at a pharmacy, which submits a claim to the Plan sponsor, and the sponsor pays the pharmacy directly or through a subcontractor. CMS reimburses the sponsor for varying portions of the prescription costs.[116]

137. To be a "covered Part D drug," a drug must be: (1) dispensable only by prescription; (2) one of the three types of "covered outpatient drug" defined in 42 U.S.C. § 1396r-8(k)(2)(A) (2016); and (3) used for a "medically accepted indication."[117]

138. The most important of these three requirements for present purposes is the third, that the drug be used for a medically accepted indication. The statute and the regulation define this term by incorporating the Medicaid definition in 42 U.S.C. §§ 1396r-8(k)(6) (2016).[118]

139. The definition is: "The term 'medically accepted indication' means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 *et seq.*] or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this

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[115] 42 U.S.C. §§ 1395w-102 (2010).

[116] *See Omnicare, Inc. v. UnitedHealth Group, Inc.*, 594 F. Supp.2d 945, 948-49 (N.D. Ill. 2009).

[117] 42 U.S.C. §§ 1395w-102(e)(1) (2010).

[118] *See* 42 U.S.C. §§ 1395w-102(e)(4)(A)(ii)(2010); 42 CFR § 423.100 (2016).

section."[119] The compendia referred to are "(I) American Hospital Formulary Service Drug Information; (II) United States Pharmacopeia-Drug Information (or its successor publications); and (III) the DRUGDEX Information System."[120]

140. The Medicare manuals provide additional guidance on Part D drug coverage. The MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL, Ch. 6, § 10.6 (Rev. 18, Jan. 15, 2016), states that a medically accepted indication "refers to the diagnosis or condition for which a drug is being prescribed, not the dose being prescribed for such indication."[121]

141. Therefore, Medicare Part D and Medicaid cover only prescription drugs used for a "medically accepted indication," which means used either for an indication approved on the Food and Drug Administration (FDA) label, or for an "off-label" indication which is "supported" by one of the approved compendia. If a drug is prescribed outside of these limitations, it is not a "covered drug," and a claim for payment based on the prescription is a false claim.

2. *Medicaid Beneficiary Opioid Use and Abuse*

142. Medicaid is a public assistance program providing for payment of medical expenses for approximately 55 million low-income patients. Funding for Medicaid is shared between the federal Government and state governments.

143. While Medicaid undoubtedly helps many deserving recipients, it also creates a series of incentives for potential abuse or diversion of opioids, which are rooted in federal law itself. Patients on Medicaid typically "pay no part of costs for covered medical expenses," other

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[119] 42 U.S.C. §§ 1396r-8(k)(6) (2016).

[120] 42 U.S.C. §§ 1396r-8(g)(1)(B)(i).

[121] *Id.*

than perhaps a small co-payment.[122] Federal law requires that Medicaid co-payments and other "cost-sharing" borne by Medicaid recipients at lower income levels be nominal. CMS has determined that states could charge those on Medicaid no more than $4 for certain classes of drugs.[123] For dangerous opioids such as oxycodone, Medicaid co-pays can run as low as $1 for as many as 240 pills—pills that can be sold for up to $4,000 on the street.

144. As one longtime local prosecutor in opioid-ravaged eastern Kentucky recounted in DREAMLAND: THE TRUE TALE OF AMERICA'S OPIATE EPIDEMIC: "We can talk morality all day long, but if you're drawing five hundred dollars a month and you have a Medicaid card that allows you to get a monthly supply of pills worth several thousand dollars, you're going to sell your pills."[124]

145. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal Government will pay for through its funding of state Medicaid programs. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered outpatient drugs." "Covered outpatient drugs" are drugs that are used for "a medically accepted indication."

3. *Medicare Beneficiary Opioid Use and Abuse*

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[122] U.S. Dep't of Health & Hum. Servs., *Frequently Asked Questions: What is the Difference* Between *Medicare and Medicaid?*, https://www.hhs.gov/answers/medicare-and-medicaid/what-is-the-difference-between-medicare-medicaid/index.html.

[123] *See* Final Rule, Medicaid and Children's Health Insurance Programs: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Eligibility and Enrollment, 78 Fed. Reg. 42159-42322 (July 15, 2013) (codified in scattered pts. of 42 C.F.R.), https://www.gpo.gov/fdsys/pkg/FR-2013-07-15/html/2013-16271.htm.

[124] Sam Quinones, DREAMLAND: THE TRUE TALE OF AMERICA'S OPIATE EPIDEMIC 211 (2015).

146. Medicare is a public health care program that provides coverage for Americans over the age of 65, as well as other persons with certain disabilities and diseases. The program is administered by third-party contractors known as "carriers," which have some discretion to make coverage determinations, but must do so within statutory and regulatory confines.

147. Starting in January 2006, Part D of the Medicare Program provided subsidized coverage for pharmacy-dispensed outpatient drugs for all beneficiaries, with low-income individuals receiving the greatest subsidies. However, a "covered Part D drug" must be used for a "medically accepted indication."

148. Medicare's Prescription Drug Program, known as Part D, provides optional drug benefits to Medicare beneficiaries. CMS contracts with private insurance companies, called sponsors, to provide Part D prescription drug coverage to beneficiaries who choose to enroll. Sponsors offer drug coverage to beneficiaries through Part D prescription drug plans. These Part D programs are subsidized by the federal Government, which covers the cost of drug payments.

149. In 2016, one out of every three beneficiaries received at least one prescription opioid through Medicare Part D. In total, 14.4 million of the 43.6 million beneficiaries enrolled in Medicare Part D received opioids. Medicare Part D paid almost $4.1 billion for 79.4 million opioid prescriptions for these beneficiaries. The vast majority of these opioids (80 percent) were Schedule II or III controlled substances, meaning they have the highest potential for abuse or diversion among legally available drugs.[125]

[125] Dept. of Health & Human Services OIG, *Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing*, 2 (July 2017), HHS OIG Data Brief OEI-20-17-00250, https://oig.hhs.gov/oei/reports/oei-02-17-00250.pdf.

150. In addition, one in ten Medicare Part D beneficiaries nationwide received opioids on a regular basis. Specifically, five million beneficiaries received opioids for three months or more in 2016. Research shows that the risk of opioid dependence increases substantially for patients receiving opioids continuously for three months. Of these five million beneficiaries, 3.6 million received opioids for six or more months and nearly 610,000 received opioids for the entire year.[126]

151. A total of 501,008 beneficiaries received high amounts of opioids through Medicare Part D in 2016. This does not include beneficiaries who had cancer or were in hospice care. Each of the 501,008 beneficiaries received an average morphine equivalent dose (MED) of greater than 120 mg a day for at least 3 months. MED is a measure that equates all the various opioids and strengths into one standard value. A daily MED of 120 mg is equivalent to taking 12 tablets a day of Vicodin 10 mg or 16 tablets a day of Percocet 5 mg. These dosages far exceed the amounts that the manufacturers recommend for both of these drugs. They also exceed the 90 mg MED level that CDC recommends avoiding for patients with chronic pain.[127]

152. As the statistics make clear, there is a real problem with inappropriate opioid prescriptions being filled by Medicare patients. Pharmacies should not be dispensing most, if not all, of the prescriptions that are clearly for excessive amounts of opioids or for patients who have been doctor shopping. However, pharmacies like Food City have failed to block these prescriptions and filled them, instead choosing to bill Medicare for medically unnecessary and/or inappropriate prescriptions.

4. *Tricare Beneficiary Coverage and Opioid Use and Abuse*

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[126] *Id.*

[127] *Id.*

153. TRICARE is the insurance plan of the U.S. Department of Defense and provides health care coverage for over 9 million beneficiaries. Approximately 20% of the covered population is active duty military, with the remainder composed of retirees, disabled personnel, and dependents.

154. Prescription drugs are an important part of the TRICARE health benefit, including coverage for opioid drugs.

155. Service members were prescribed pain medication at a rate four times higher in 2009 than in 2001.[128] Chronic pain medication and opioid use rates in the military, specifically in Service members returning from Afghanistan, were estimated at approximately 44% and 15%, respectively.[129] Most of the prescription drugs misused by Service members are opiate pain medications, which include codeine, morphine, oxycodone, oxymorphone, hydrocodone, and hydromorphone. Combat-related injuries may help explain the increase in prescriptions and the corresponding increase in self-reported misuse of prescription drugs. Post-traumatic stress and other mental health disorders are associated with substance misuse, as are other problems experienced by returning military personnel, including sleep disturbances, traumatic brain injury, and unemployment.[130]

156. Military physicians wrote nearly 3.8 million prescriptions for pain medication in 2009, more than quadruple the number of such prescriptions written in 2001.[131] However, in the

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[128] Institute of Medicine (IOM), 2012.

[129] R.L. Toblin, P.J. Quartana, L.A. Riviere, K. Walper, C.W. Hoge, *Chronic pain and opioid use in U.S. soldiers after combat deployment*, 174 JAMA Internal Medicine 1400-1401 (2014).

[130] National Institute on Drug Abuse (2013): *Drug Facts: Substance Abuse in the Military*, Retrieved from http://www.drugabuse.gov/publications/drugfacts/substance-abuse-inmilitary.

[131] Institute of Medicine, *Substance Use Disorders in the US Armed Forces*, National Academies Press (2013) https://www.nap.edu/catalog/13441/substance-use-disorders-in-the-us-armed-forces.

past few years, self-reported use of both prescription opioid pain relievers and use of sedatives has decreased among active duty personnel. From 2011 to 2015, the percentage of service members using pain relievers in the past month decreased by nearly half, likely reflecting prevention and appropriate prescribing initiatives set in motion by the Department of Defense.[132] Nonetheless, these medications were misused and overused more often than other drugs. Prescription drug misuse was highest in the Army and lowest in the Coast Guard.[133]

157. Opioid use disorders among military personnel often begin with a opioid pain prescription following an injury during deployment. However, due to the addictive nature of opioids, particularly coupled with mental health struggles experienced by some military service men and women, regular use of opioids can lead to addiction.

158. Many veterans have unique issues related to pain management, with two-thirds reporting they experience pain.[134] More than 9% reported that they experience severe pain, compared to only 6.4% of non-veterans, putting them at higher risk for accidental opioid pain reliever overdoses.[135] From 2001 to 2009, the percent of veterans in the VHA system receiving an

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[132] Lin, L.A., Bohnert, A.S., Kerns, R.D., *et al.*, Impact of the Opioid Safety Initiative on Opioid-Related Prescribing in Veterans, 158 Pain 833-839 (2017).

[133] Meadows, S.O., Engel, C.C, Collins, R.L, *et al.*, *Health Related Behaviors Survey: Substance Use Among U.S. Active-Duty Service Members*, RAND Corporation, 2018, **Error! Hyperlink reference not valid.**https://www.rand.org/pubs/research_briefs/RB9955z7.html.

[134] Nahin R. L., Severe pain in veterans: The effect of age and sex, and comparisons with the general population, 18 The Journal of Pain 247–254 (2017).

[135] *Id.*

opioid prescription increased from 17% to 24%.[136] Similarly, the overall opioid overdose rates of veterans increased to 21% in 2016 from 14% in 2010.[137]

5. *Federal Employee Health Benefit Program Beneficiary Coverage and Opioid Use and Abuse*

159. The Federal Employees Health Benefits ("FEHB") Program is a system in which employee health benefits are provided to civilian government employees and annuitants of the United States government. The FEHB Program covers some nine million federal civilian employees, retirees, former employees, and their families. The FEHB Program is voluntary and is financed through employee and employer contributions.

160. Prescription drug coverage, available at retail and mail service pharmacies, is a key component of the FEHB Program's benefit design.

161. The opioid crisis has had a significant impact on the FEHB Program, including:

- The largest FEHB Program carrier reported a 300% increase from 2012 through 2017 in the identification of beneficiaries potentially abusing prescription opioid medications;
- The number of prescriptions for Narcan, Nalaxone and Evzio, drugs used to thwart opioid-related overdoses, doubled from 2016 through 2017;
- In 2017, the percentage of FEHB Program members enrolled in employee organization fee-for-service plans taking opioid prescriptions ranged between 17.8 percent and 24.3 percent of total beneficiaries; and

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[136] Teeters, J.B., Lancaster, C.L., Brown, D.G., & Back, S.E., *Substance use disorders in military veterans: prevalence and treatment challenges*, 8 Substance Abuse and Rehabilitation 69-77 (2017).

[137] Lewei, A.L., Peltzman, T., McCarthy, J.F., *et al.*, *Changing trends in opioid overdose deaths and prescription opioid receipt among veterans*, 57 American Journal of Preventive Medicine 106-110 (2019).

- FEHB Program ancillary costs for treatment of substance abuse have risen sharply at a rate of nearly 283 percent, from 2013 through 2016.[138]

6. *Other Government Health Care Program Beneficiary Coverage and Opioid Use and Abuse*

162. Georgia, Kentucky, Tennessee, and Virginia state governments provide some form of health insurance coverage for their employees, retirees, as well as their beneficiaries and survivors.

163. In 2017, there were numerous state employees and families covered by employer health insurance in Georgia, Kentucky, Tennessee, and Virginia. Local government employees in Georgia, Kentucky, Tennessee, and Virginia are similarly covered. Comprehensive prescription drug coverage, including for opioid drugs, is a key feature of the benefits offered to Georgia, Kentucky, Tennessee, and Virginia state and local government employees, retirees as well as their beneficiaries and survivors, including coverage for prescription opioid drugs.

164. In addition, the Children's Health Insurance Program ("CHIP") is a partnership between the federal and state governments that provides low-cost health coverage to children in families that earn too much money to qualify for Medicaid. All states provide comprehensive coverage for prescription drugs through CHIP, including coverage for opioid drugs.

165. Georgia, Kentucky, Tennessee, and Virginia state governments also offer prisoners coverage for prescription opioid drugs.

166. These other Government Programs have also experienced widespread abuse and diversion of opioids.

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[138] U.S. Office of Personnel Management, Office of the Inspector General, *Top Management Challenges: Fiscal Year 2018*, Nov. 5, 2018, at 7-8, https://www.opm.gov/our-inspector-general/publications/special-reports-and-reviews/2018-top-management-challenges.pdf.

167. For example, a significant percentage of the nation's prison and jail population suffers from drug addiction. The Bureau of Justice Statistics (BJS), part of the U.S. Department of Justice (DOJ), estimated in a 2017 report that two-thirds of offenders held in state prisons and local jails had substance abuse problems, yet only a quarter of that group received adequate drug treatment.

168. A 2016 study published in *Substance Abuse and Rehabilitation* estimated that between 24% and 36% of opioid-dependent adults cycle in and out of jails each year, creating a cycle between drug addiction and incarceration.

D. Federal Guidance Governing Pharmacy Dispensing of Opioids

169. The CDC has published guidelines regarding the proper use of opioids.[139] The guidelines explicitly state that "Opioid pain medication use presents serious risks, including overdose and opioid use disorder."[140] Furthermore, "[s]ales of opioid pain medication have increased in parallel with opioid-related overdose deaths."[141]

170. The CDC guidelines, and many state laws, rely on Milligram Equivalents ("MME"). As the name suggests, MME is an opioid's dosage's equivalency to morphine. Using MME is useful because it provides a constant metric to compare opioids of varying types, strengths, and delivery methods. This is particularly useful for patients who may be using a combination of different opioid products or have changed products over time.

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[139] U.S. Centers for Disease Control, *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, 65 Morb. And Mort. Wkly. Rep. (March 18, 2016).

[140] *Id.*

[141] *Id.*

171. The CDC has a conversion chart of the most common opioids in milligrams (mg) to MMEs.[142] So, for example, 10 tablets of hydrocodone/acetaminophen 5mg/300mg would equal 50 MME (10 tablets x 5mg of hydrocodone x 1 hydrocodone oxycodone conversion factor = 50 MME). 2 tablets of oxycodone 30mg would equal 90 MME (2 tablets x 30mg of oxycodone x 1.5 oxycodone conversion factor = 90 MME).[143]

172. The CDC has determined that in "[h]aving a history of a prescription for an opioid pain medication increases the risk for overdose and opioid use disorder, highlighting the value of guidance on safer prescribing practices for clinicians. For example, a recent study of patients aged 15–64 years receiving opioids for chronic non-cancer pain and followed for up to 13 years revealed that one in 550 patients died from opioid-related overdose at a median of 2.6 years from their first opioid prescription, and one in 32 patients who escalated to opioid dosages >200 morphine milligram equivalents (MME) died from opioid-related overdose."[144]

173. In addition, the CDC found that "opioid-related overdose risk is dose-dependent, with higher opioid dosages associated with increased overdose risk. [Four studies] evaluated similar MME/day dose ranges for association with overdose risk. In these four studies, compared with opioids prescribed at <20 MME/day, the odds of overdose among patients prescribed opioids for chronic non-malignant pain were between 1.3 and 1.9 for dosages of 20 to <50 MME/day,

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[142] Opioid Oral Morphine Milligram Equivalent (MME) Conversion Factors, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Opioid-Morphine-EQ-Conversion-Factors-Aug-2017.pdf.

[143] U.S. Centers for Disease Control, *Calculating Total Daily Dose of Opioids for Safer Dosage*, https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.

[144] U.S. Centers for Disease Control, *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, 65 Morb. And Mort. Wkly Rep. (March 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.

between 1.9 and 4.6 for dosages of 50 to <100 MME/day, and between 2.0 and 8.9 for dosages of ≥100 MME/day. Compared with dosages of 1-<20 MME/day, absolute risk difference approximation for 50-<100 MME/day was 0.15% for fatal overdose and 1.40% for any overdose, and for ≥100 MME/day was 0.25% for fatal overdose and 4.04% for any overdose."[145]

174. "A recent study of Veterans Health Administration patients with chronic pain found that patients who died of overdoses related to opioids were prescribed higher opioid dosages (mean: 98 MME/day; median: 60 MME/day) than controls (mean: 48 MME/day, median: 25 MME/day). Finally, another recent study of overdose deaths among state residents with and without opioid prescriptions revealed that prescription opioid-related overdose mortality rates rose rapidly up to prescribed doses of 200 MME/day, after which the mortality rates continued to increase but grew more gradually."[146]

175. Furthermore, "epidemiologic studies suggest that concurrent use of benzodiazepines and opioids might put patients at greater risk for potentially fatal overdose. Three studies of fatal overdose deaths found evidence of concurrent benzodiazepine use in 31%–61% of decedents. In one of these studies, among decedents who received an opioid prescription, those whose deaths were related to opioids were more likely to have obtained opioids from multiple physicians and pharmacies than decedents whose deaths were not related to opioids."[147]

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[145] *Id.*

[146] *Id.*

[147] *Id.*

176. "[M]ost fatal overdoses could be identified retrospectively on the basis of two pieces of information, multiple prescribers and high total daily opioid dosage, both important risk factors for overdose that are available to prescribers in the PDMP."[148]

177. In those guidelines, the CDC recommends numerous strategies to reduce inappropriate opioid prescribing. Of particular relevance here, the CDC recommends that clinicians "should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day."[149]

178. Dosages at or above 50 MME/day increase the risks of overdose by at least 2x over the risk at <20 MME/day. In a national sample of Veterans Health Administration (VHA) patients with chronic pain receiving opioids from 2004–2009, patients who died of opioid overdose were prescribed an average of 98 MME/day, while other patients were prescribed an average of 48 MME/day.[150]

E. State Laws Governing Pharmacy Dispensing of Opioids

179. Over half of all states have enacted laws that restrict the prescribing or dispensing of opioids for acute pain. Fifteen states have passed laws limiting opioid prescribing for acute pain in an opioid naive patient to a seven-day supply.[151]

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[148] *Id.*

[149] U.S. Centers for Disease Control *Guidelines for Prescribing Opioids for Chronic Pain*, https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf.

[150] U.S. Centers for Disease Control, *Calculating Total Daily Dose of Opioids for Safer Dosage*, https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.

[151] *Id.*

180. Among the states with the strictest limits are Tennessee and Kentucky, where initial prescribing is limited to three to four days.[152]

181. When addressing risks for drug overdose, studies support the need to monitor not only duration of initial therapy, but also total daily dosing for patients. Tennessee allows 60 MME per day if it is for 3 days or less. Otherwise the prescriptions are restricted to 50 MME daily.[153]

182. Rather than setting opioid limits by statute, a few state laws direct or authorize other entities to do so (*e.g.*, Virginia). These entities may include the Department of Health, a designated state health official, or regulatory boards, such as the Board of Medicine, Nursing and/or Dentistry.

183. Consequently, the dispensing of controlled substances, when faced with warning signals and without first ensuring that the prescription was issued for a legitimate purpose by a practitioner acting in the usual course of professional practice, violates the pharmacist's corresponding responsibility under the CSA[154] to ensure the legitimacy of the prescription[155] as well as pharmacy laws and regulations in a majority of the states.

184. Prescribing or dispensing controlled substances in amounts or for durations that are not medically necessary is beyond the scope of professional practice. Prescribing or dispensing controlled substances for pain will be considered to be for a legitimate medical purpose in certain narrow circumstances, including after a documented medical history, pursuant to a written treatment plan with stated objectives, and considering the risk of medication misuse or diversion.

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[152] *Id.*

[153] *Id.*

[154] 21 U.S.C. § 842(a) (prohibiting distributing or dispensing in violation of the prescription provisions of 21 U.S.C. § 829).

[155] 21 C.F.R. § 1306.04 and 21 U.S.C. § 841(a) (prohibiting dispensing except as authorized by the CSA) because the prescription was filled outside of the pharmacist's usual course of professional practice. *See also* 21 C.F.R. § 1306.06.

F. State Prescription Drug Monitoring Programs to Counter Doctor and Pharmacy Shopping

185. It is undeniable that illicit street opiates and prescription opioid medications can often be linked, with legitimate prescriptions initiating the addiction, often followed by the person seeking the chemical from illegal sources once the prescription has ended. Sometimes, however, they will resort to "doctor shopping" – i.e., visiting multiple physicians in various ambulatory settings to obtain more of the same opioid medications if the patient's own health care provider is unwilling or unable to renew or refill the prescription. State prescription drug monitoring programs ("PDMPs") make a significant contribution to fighting the opioid epidemic by preventing and inhibiting doctor shopping.

186. PDMPs, or PMPs (prescription monitoring programs), as they are alternatively known, are utilized by 49 states, as well as Guam and the District of Columbia.[156] Although requirements vary by state, they generally collect data from dispensers and report to authorized users of a state's database the number of prescriptions that have been filled for scheduled drugs for each recipient. Access to the information contained in such databases is typically limited to prescribers and state officials. State pharmacy boards and health departments operate most PDMPs, but a minority relies on professional licensing agencies, law enforcement, state substance abuse agencies, or in the case of Connecticut, the Department of Consumer Protection.

187. All PDMPs monitor at least Schedule II through IV Drugs, with some also monitoring Schedule V and "Drugs of Concern" as designated by an authorized state agency.

[156] Missouri is the only state not to have a statewide PDMP, though an Executive Order was issued in July 2017 directing its formulation. PDMP TTAC, *Status of Prescription Drug Monitoring Programs (PDMP)*, www.pdmpassist.org/pdf/PDMP_Program_Status_20170824.pdf.

Eighteen states and the District of Columbia maintain a voluntary system, with no mandatory enrollment required of either prescribers or dispensers.[157]

188. Still, the majority of state legislatures understand that the sum total is only as good as its parts. For example, recent Georgia legislation tied mandatory PMDP registration to the licensed practitioner's ability to secure or renew a DEA number.[158] In an effort to combat the opioid epidemic through ensuring reliable information is accessible to prescribers, Kentucky has added penalties for failure of pharmacies to comply with reporting requirements, including sanctions and a monetary penalty per offense.[159]

189. Statutory requirements for submitting and gathering prescription data are of little value if the statutes fail to specify how the data will be used. Some states (*e.g.*, Georgia) do not require query of all controlled substance prescriptions in certain situations. For example, the query requirement may not be applicable to providers of certain specialties if the prescription is for less than a three-day supply and contains less than 26 pills, the patient is terminally ill, or when the controlled substance is administered in a hospital. Georgia's legislature added consequences for those practitioners who fail to query the PDMP, requiring them to be reported to their licensure boards for disciplinary action.[160]

190. Mandatory use of PDMP programs has proven successful. In 2011 and 2012 respectively, Kentucky mandated clinicians to review PDMP data and implemented pain clinic

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[157] PDMP TTAC, *PDMP Mandatory Query by Prescribers and Dispensers*, www.pdmpassist.org/pdf/Mandatory_Query_20170824.pdf .

[158] H.B. 249 (Ga. 2017), www.legis.ga.gov/Legislation/20172018/170657.pdf [hereinafter H.B. 249]; H.B. 1032 (Miss. 2017), http://billstatus.ls.state.ms.us/2017/pdf/history/HB/HB1032.xml.

[159] H.B. 314 (Ky. 2017); H.B. 243 (N.C. 2017).

[160] *See* H.B. 3824 (S.C. 2017), https://www.scstatehouse.gov/sess122_2017-2018/bills/3824.htm; H.B. 249 (Georgia 2017). http://www.legis.ga.gov/Legislation/20172018/170657.pdf.

regulation. Tennessee, starting in 2012, required prescribers to check the state's PDMP before prescribing opioids. In 2013, Tennessee saw a 36 percent drop in patients seeing multiple prescribers for the same drugs.

191. Research has shed light on how a PDMP affects these Medicare patient behaviors.[161] A study compared Medicare opioid prescription data in 10 states that enacted use mandates from 2007-2013 with 17 other states implementing PDMPs without use mandates. In states with mandates, the percentage of Medicare enrollees who obtained prescriptions from five or more doctors was eight percent lower, compared with other states. The percentage of people getting opioids from five or more pharmacies was 15 percent lower.[162]

192. States with use mandates also saw a decline in the number of Medicare enrollees filling opioid prescriptions before the previous one had run out or obtaining more than a seven-month supply of opioids in a half-year period. These states also saw a 15 percent reduction in the number of Medicare enrollees with four or more new patient visits in six months. The authors estimate that Medicare would save $348 million annually in unnecessary new patient visits if every state mandated use of its PDMP.[163]

G. Unlawfulness of a Prescription Is Material to Government Programs' Payment

193. Compliance with federal and state requirements relating to pharmacies' dispensing of controlled substances was and remains material to Government Programs' decision to pay Food City's claims for reimbursement of controlled substances. Compliance with these requirements is

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[161] Nat'l Bureau Econ. Res. Working Paper Series, *The Effect of Prescription Drug Monitoring Programs on Opioid Utilization in Medicare* 23148 (2017), https://www.nber.org/papers/w23148.pdf.

[162] *Id.*

[163] *Id.*

central to Government Program benefits and is a condition of these medications being covered by these programs.

194. Government Programs routinely deny payment for controlled substance medications, or seek to recoup payments already made, when such prescriptions are not issued or dispensed for a legitimate medical purpose in the usual course of professional practice or when the controlled substance medication is intended for purposes of addiction or recreational abuse. For example, DOJ has litigated or settled numerous actions where it was alleged that medical providers and/or pharmacies submitted claims for controlled substance medications to Government Program members that lacked a valid prescription, were not for a legitimate medical purpose and lacked a medically accepted indication, or that did not comply with State law.

195. The HHS Secretary's declaration that the opioid epidemic is a national public health emergency under federal law reflects the government's stance to deny payment for improperly dispensed controlled substances.

196. Accordingly, at all times material hereto, Food City knew or should have known that Government Programs would not pay for claims submitted if they knew that the controlled substance prescriptions at issue were invalid, did not comply with federal and/or state law, and/or lacked a legitimate medical purpose for a medically accepted indication. Alternatively, Food City knew or had reason to know that these Programs would not pay claims submitted to them if they knew that the controlled substance prescriptions were otherwise invalid.

VI. BACKGROUND

197. At all times material hereto, Food City dispensed unreasonable dosages, quantities, and combinations of opioids throughout Georgia, Kentucky, Tennessee, and Virginia (and in this District) from its 106 retail pharmacies despite being on notice of red flags of abuse and diversion,

in violation of its duties as a pharmacy under the CSA and Georgia, Kentucky, Tennessee, and Virginia state pharmacy laws and regulations.

198. At all times material hereto, Food City has operated a network of some 106 pharmacies throughout Georgia, Kentucky, Tennessee, and Virginia, which have dispensed massive quantities of opioids, fueling the opioid epidemic. In so doing, Food City violated its obligations under the CSA and Georgia, Kentucky, Tennessee, and Virginia state pharmacy laws and regulations as a pharmacy to prevent abuse and diversion.

A. Food City Was Well Aware of the Opioid Crisis and Failed to Take Steps to Curtail and Prevent Expansion of the Problem at Its Stores

199. Food City has had knowledge and/or notice of the opioid problem since at least 2008. At any time since, Food City could have easily taken steps to curtail and prevent expansion of the problem, but it failed to do so because it was chasing the profit that wantonly and illegally dispensing opioids promised.

200. Food City was well aware of the problem of the opioid epidemic. For example, throughout the growing opioid epidemic, there have been widespread reports of robberies and burglaries at its pharmacies tied to narcotics. Food City pharmacies experienced numerous instances of forgery, fraud, theft, and robbery by addicts and criminals seeking oxycodone and similar CII drugs. A review of local news reveals repeated instances of prescription fraud, theft, robberies, and armed robbery. The rampant, opioid-related crime afflicting its pharmacies across Georgia, Kentucky, Tennessee, and Virginia could not have gone unnoticed by Food City.

201. In September 2007, 52-year-old Nicki Shackleford had just picked up her prescriptions from the Bearden Food City Store No. 674 in Knoxville and was walking from the store to her car when 34-year-old John Nicely grabbed her, maced her, and took off with her prescription medications. Violence related to addiction to pain killers was becoming an increasing

problem at Food City pharmacies. According to the Knoxville, Tennessee police spokesman: "That's usually what drives this type of thing is the need for drugs. So they can turn violent if they get very desperate they can take extreme measures to try to fill their need."[164]

202. On November 28, 2009, Brian Tweed, 32, of Dayton, Ohio, was taken into custody at a convenience store at Emory Road and Dry Gap by Patrol Officer Ernie Bowman. Tweed had allegedly entered the pharmacy area of the Food City No. 616 on Hardin Valley Road in Knoxville about 1 p.m., pulled a silver revolver and demanded a clerk fill a bag with pain medication. The clerk complied, and the suspect went out a side door where a witness saw him leave in a Range Rover.[165]

203. Bobby Wright and James Melton were arrested for an armed robbery at the Bearden Food City No. 674 in Knoxville on July 13, 2010.[166]

204. The Lenoir City Food City No. 650 was robbed on New Year's Eve, December 31, 2010 around noon Friday after a 6-foot white male weighing around 189 pounds handed a Food City employee a note asking for oxycodone and Opana, a narcotic pain medicine. The note also stated the robber had other people in the store with him and the clerk should not do anything stupid and stated, "You don't want to get hurt."[167]

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[164] *Protecting Yourself at the Pharmacy*, WVLT – Knoxville, Tennessee (September 11, 2007).

[165] *KCSO nabs armed robbery suspect in short order*, Knoxville News Sentinel (Nov. 2009), http://archive.knoxnews.com/news/local/kcso-nabs-armed-robbery-suspect-in-short-order-ep-409297012-359066831.html/.

[166] Report and Recommendation, *United States v. Jason James Melton*, No. 3:10-CR-126 (E.D. Tenn. (Feb. 7, 2012), https://www.govinfo.gov/content/pkg/USCOURTS-tned-3_10-cr-00126/pdf/USCOURTS-tned-3_10-cr-00126-1.pdf.

[167] *Two businesses robbed in Lenoir City*, Lenoir City News-Herald (Jan. 3, 2011).

205. At approximately 3:30 in the afternoon on August 8, 2013, Church Hill, Tennessee police responded to a report of an armed robbery at Food City No. 603. The assailant allegedly handed a note to a pharmacist demanding a list of various narcotic drugs, along with a threat that "all pharmacy workers will die" if the drugs were not handed over. Police say Arthur also verbally stated to one employee that he would shoot them all if he did not get the narcotics in 20 seconds.[168]

206. Newport, Tennessee police say Wendy Cochran, 40, was arrested on October 3, 2013 on drug fraud charges. The woman allegedly called in fraudulent prescriptions to the Food City No. 604, 416 Eastern Plaza Center, Newport, Tennessee, saying she was from the office of a Knoxville physician. Cochran called in prescriptions for hydrocodone and antihistamine. She told police she was addicted to hydrocodone and was awaiting admission to a treatment center.[169]

207. Crime in and around Food City Store No. 674 located at the Bearden Center, Knoxville, Tennessee got so bad that, according to Food City Employee No. 16, an uncertified pharmacy technician at the Food City pharmacy, the store hired two off-duty police to monitor the store. The police not only guarded the store and parking lot, they escorted customers and employees to their cars. According to this former employee, police made sure employees did not get hurt and made sure no drug deals went down in the parking lot and that the patients could get to their cars without somebody holding them up.

208. A former employee at Food City No. 616 located at 11501 Hardin Valley Road, Knoxville, Tennessee, said he observed "obvious drug deals and drug exchanges" that took place in the store's parking lot. The interactions could be seen on security camera footage, he said. "They

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[168] Rain Smith, *Suspect arrested in robbery of Church Hill's Food City pharmacy*, TimesNews.net (Aug. 15, 2013).

[169] *Cochran charged with drug fraud*, WNPC.com (Oct. 5, 2013), http://www.923wnpc.com/cgi-bin/newspost/viewnews.cgi?category=1&id=1380971543.

were pretty clear as day," he said about being able to recognize that the interactions were drug deals.

209. Pain clinics and pill mills drive the narcotic burglary problem at pharmacies and the robberies mirror a national rise in the abuse and diversion of narcotic painkillers. The robberies, many of which happened at Food City pharmacies, put Food City on notice of the growing opioid epidemic across Georgia, Kentucky, Tennessee and Virginia.

210. Food City was well aware of doctors operating pill mills were sending patients to fill their prescriptions at its pharmacies.

211. Even while its pharmacies actively filled voluminous numbers of inappropriate and medically unnecessary prescriptions throughout Georgia, Kentucky, Tennessee and Virginia, Food City paid only lip service to efforts to combat the opioid epidemic. For example, Food City actively participated in the 2012 Southwest Virginia Prescription Drug Abuse Summit put on by the United States Attorney for the Western District of Virginia, Timothy J. Heaphy.

212. Food City Director of Human Resources Donnie Meadows was a participant at the November 14, 2012 Summit held in Wytheville, Virginia. The aim of the Summit was "to bring law enforcement, service providers and leaders of commerce and their communities together to engage in an open and direct discussion about the impact the abuse of prescription drugs."[170]

213. Following the Summit, U.S. Attorney Heaphy issued a Report declaring "abuse of prescription drugs is at crisis proportions in the United States, reported by the Centers for Disease Control and Prevention as an epidemic, and overshadowing other serious substance abuse

[170] Southwest Virginia Prescription Drug Abuse Summit, https://www.justice.gov/sites/default/files/usao-wdva/legacy/2012/12/13/drugsummit_bios.pdf.

problems in the country. Appalachia is particularly hard hit; the sparse population of Southwest Virginia is impacted at alarmingly higher rates than the rest of the Commonwealth."[171]

214. The Report included chilling numbers demonstrating the majority of drug-related deaths in the region were the result of prescription drugs:

> According to the Office of the Chief Medical Examiner for the Western District of Virginia, drug deaths have increased throughout Virginia over 80 percent since 1999 and 41 percent in Western Virginia from 2007 to 2011. In 2010, the majority of drug-related deaths were accidental. Fentanyl, hydrocodone, methadone and oxycodone, all prescription opioids, were found to be wholly responsible for 53.8 percent of drug-only deaths.[172]

215. The Report also detailed the impact the epidemic had on law enforcement in the region:

> Since the mid-1990's, as much as 85 percent of all drug cases in Lee, Scott, Wise, and Dickenson counties involve prescription drugs. These four counties are home to only 1 percent of Virginia's population, yet the Virginia State Police spent 25 percent of their statewide, undercover purchase funds buying prescription medications here in FY 2011. In Wise County, nearly 70 percent of the total police caseload is directly related to drug abuse. There are approximately 2,000 active felony cases in the region, the highest in the state when compared to population.[173]

216. The Summit found that a key part of the problem was lack of training, including the lack of pharmacist training "on appropriate treatment of chronic pain, substance abuse, and addiction. They are not trained on diversion or identification of patients with patterns of medication misuse." Therefore, many pharmacists are "dispensing controlled substances without the

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[171] Prescription Drug Abuse in Southwest Virginia: Recommendations from the Summit, November 14, 2012 Wytheville, Virginia, at 1, https://www.justice.gov/sites/default/files/usao-wdva/legacy/2013/04/17/summit%20report_final20130417.pdf.

[172] *Id.*

[173] *Id.* at 3.

appropriate knowledge base to apply key standards of care in these difficult patient populations."[174]

217. Similar efforts were under way elsewhere in the region where Food City pharmacies operated. For example, then Kentucky Attorney General Jack Conway in 2012 joined a national effort aimed at preventing prescription abuse and diversion. "Prescription drug abuse is an all hands on deck issue," Conway said in a statement. According to Conway: "Non-medical use or abuse of prescription painkillers is the fastest-growing drug problem in the United States and it is killing our kids," Conway said. "This is an epidemic that is beginning in homes across Kentucky and the nation."[175]

218. Food City was also involved in other government efforts to control the opioid epidemic in the region. Even while Food City Executive Vice President Mickey Blazer was pressuring Food City pharmacies to fill as many opioid prescriptions as possible, he was also a member of the Virginia Governor's Task Force on Prescription Drug and Heroin Abuse, a 32-member multi-disciplinary Task Force set up by then-Governor Terry McAuliffe on September 24, 2014 "to respond to the growing opioid and heroin overdose epidemic that has taken the lives of thousands of Virginians."[176]

219. The Report issued by the Governor's Task Force, of which EVP Blazer was a member, described the problem: "In Virginia, overdose deaths are occurring in all parts of the state and across all walks of life. The number of these fatalities is steadily rising. For some

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[174] *Id.* at 8.

[175] Associated Press, *Ky. part of national prescription drug initiatives*, Denver Post (Sept. 21, 2012), https://www.denverpost.com/2012/09/21/ky-part-of-national-prescription-drug-initiatives/.

[176] Recommendations of the Governor's Task Force on Prescription Drug and Heroin Abuse Implementation Plan – Update, Fall 2015 (Oct. 20, 2015).

individuals, prescription opioids are just the beginning; what begins as abuse, misuse, or overuse of a prescription opioid can evolve into the use of heroin, which is often cheaper and easier to obtain but has very similar effects."[177]

220. Yet, in spite of its clear awareness of rampant problems going with prescription drug abuse and diversion, Food City did nothing to stop the opioid epidemic (including its dispensing practices fueling the oversaturation of opioids into communities) and did not implement any changes in its operations to combat the root causes of the epidemic and corresponding abuse and diversion its wanton dispensing practices stoked.

221. Not only that, but many of those in Food City senior management like EVP Mickey Blazer, Manager of Pharmacy Operations Ken Slagle, and Pharmacy Services Supervisor Tom Geoghagan, who had been instrumental in insisting that its pharmacies dispense wildly inappropriate quantities of questionable opioid prescriptions, still remain in senior positions with the company even today.

222. Even more troubling, in what can only be described as the fox guarding the henhouse,[178] especially in light of the serious violations found at Tennessee Food City Stores Nos. 674, 694 and 616, *see infra* ¶ 247, Food City senior management employee Melissa McCall has actually been appointed to the very same Tennessee State Board of Pharmacy which had just years before sanctioned the stores for flagrant opioid dispensing violations.

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[177] *Id.* at 4.

[178] *See* Rebecca Haw Allensworth, *Licensed to Pill*, New York Review of Books (July 7, 2020), https://www.nybooks.com/daily/2020/07/21/licensed-to-pill/ (But . . . licensing boards, which have the final say in whether a [medical professional] will be allowed to continue to practice and prescribe, are treating cases of unethical prescribing with a leniency that's at odds with the scope of the crisis."); *see also* Rebecca Haw Allensworth, Foxes at the Henhouse: Occupational Licensing Boards Up Close, 105 California Law Review 1567 (2017), https://scholarship.law.vanderbilt.edu/faculty-publications/11/.

223. On November 9, 2018, Melissa McCall, Pharmacy Professional Services Manager was nominated by Tennessee Governor Bill Haslam to serve a six-year term on the Tennessee Board of Pharmacy.[179] McCall is responsible for compliance at thirty-eight Food City pharmacies spread across Northeast Tennessee, Southwest Virginia and Eastern Kentucky, including Knoxville Food City Stores Nos. 674, 694 and 616. At the time, Food City EVP Blazer commented on how she would be an "asset" to the Board: "Her high level of commitment to her patients and the practice of Pharmacy will certainly be an asset to the Tennessee Board of Pharmacy."[180]

224. Yet, the Tennessee Attorney General in the State's lawsuit filed 10 months later against the company's drug distributor, AmerisourceBergen, alleges that the huge volumes of opioids ordered by Knoxville Food City Stores Nos. 674, 694 and 616 "were so high that they were indicators of diversion or otherwise illegitimate prescriptions on their face."[181]

225. For example, on November 2, 2010, in a single day, Food City No. 674 had ordered *180,000 tablets of immediate release oxycodone*, 93% of which was for Oxycontin 30.[182]

B. Food City Only Cared About Profit and Had No Policies and Procedures to Prevent Illegal Dispensing

226. Food City's singular role in fueling the opioid crisis throughout Georgia, Kentucky, Tennessee, and Virginia and its attendant harms to the Government Programs has been spurred by the company's overarching goal of profitability above all else. Even while the opioid

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[179] Food City Press Release, https://www.foodcity.com/community/news/293/ (Nov. 9, 2018).

[180] *McCall appointed to Tennessee Board of Pharmacy*, TimesNews (Nov. 16, 2018), https://www.timesnews.net/mccall-appointed-to-tennessee-board-of-pharmacy/article_943a340f-7109-5ffe-af4f-24a707567a23.html.

[181] See Complaint, *State of Tennessee ex rel. Herbert H. Slatery III, Attorney General v. AmeriSource Bergen Drug Corporation*, Cir. Ct of Knox County, 6th Judicial Dist. (Knoxville) (Oct. 3, 2019), at ¶ 194.

[182] *Id.* at ¶ 194.

epidemic has raged throughout Georgia, Kentucky, Tennessee and Virginia, Food City came to rely on its pharmacies as profit centers for the company. For its pharmacies to be profitable, however, they needed to dispense large amounts of the prescriptions with the highest profit margins. Unfortunately, those prescriptions are opioid prescriptions. Coupled with a company that has almost no institutional expertise in pharmacy operations—much less any real commitment to compliance with the laws governing controlled substances—the result was sadly predictable. Food City pressured its pharmacies to dispense as many opioid prescriptions as possible and completely abdicated its legal duties to ensure legal dispensing of addictive and dangerous controlled substances.

227. A pressure point for pharmacy profitability was The Affordable Care Act signed into law in 2010. The legislation greatly reduced the reimbursements pharmacies would get from Government Programs. By 2013, pharmacy reimbursements were down over 20 percent.[183]

228. Reduced pharmacy reimbursements could only be offset by filling a greater number of prescriptions. Unfortunately for the public and Government Programs, the timing was perfect for Food City to capitalize on the opioid epidemic's explosion of pills to recoup the lost reimbursements by filling an even greater volume of prescriptions.

229. Food City's singular focus on filling all prescriptions to drive profits was enabled by a total lack of rigorous dispensing protocols or policies. Such policies would not have only resulted in denying more inappropriate prescriptions, but also would have slowed down the speed at which prescriptions were filled. Instead, Food City has insisted its dispensing practices operate as a production line which rewarded volume and penalized attention to patient care.

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[183] Adam J. Fein, Ph.D., *Obamacare Will Squeeze Pharmacy Profits* (Oct. 8, 2013), https://www.drugchannels.net/2013/10/obamacare-will-squeeze-pharmacy-profits.html.

230. Food City has next to nothing in the way of checklists, guidance, training, or resources for pharmacists or technicians to consult about whether a prescription was medically appropriate and should or should not be filled. Even to the extent that Food City had policies and procedures, Food City rarely emphasized or enforced those policies.

231. Even if a pharmacist or technician did identify a prescription that was not medically appropriate, there has been a total lack of policies and procedures for the pharmacist to follow after identification. Food City has had no protocols about how to flag prescribers who consistently were writing medically unnecessary and/or inappropriate prescriptions, no protocols about how to flag prescription shopping by customers, and no protocols how they were to communicate information about trends they were seeing.

232. Food City pharmacies essentially left the pharmacists and technicians on their own to evaluate prescriptions. In doing so, Food City abdicated its legal duty to leverage the information it had as a chain pharmacy to assist its pharmacists exercise their corresponding responsibility.

233. This has led to endemic inconsistency, with many simply choosing to fill as many prescriptions as possible. This was especially true given the pressures and incentives built into the structure of Food City pharmacies' operations not to question prescriptions and to fill as many as possible, as quickly as possible.

234. According to Food City Employee No. 15 (the former Food City Pharmacy Director of Pharmacy), when pharmacy technicians at a Food City location called in sick or were absent for some other reason, the company regularly had clerks from its grocery stores fill in, even though they were not trained on HIPAA or pharmacy practices, he said, adding that the company refused to bring in other pharmacy technicians because it would have had to pay them overtime.

235. "They looked at it like you had to do whatever you had to do at the time," Employee No. 15 said. "I said, 'We're creating a potential problem.'"

236. Instead, Employee No. 15 said he "became the problem" in the eyes of the company. "I was the one who wasn't a team player or company player," he said. "You knew it from going into stores – you knew which stores had control issues. But when everybody's happy and everything's going good and the district manager is smiling and [saying] 'everything's going great in that store' and 'everything's growing,' it's hard to put the damper on that."

237. Food City did not have any policies or procedures related to dispensing opioids or other controlled substances, Food City Employee No. 15 said. "Zero policies," he said. "From my viewpoint, looking back it's probably something I should have done. That's not something that the company wanted me to do. They never addressed controlleds or opiates. It was never discussed."

238. District managers' bonuses were tied to sales, which meant they had no incentive to curb growth at pharmacies that were dispensing a high volume of opioids and controlled substances, he explained. "CII drugs cost a lot," he said.

239. With many of its pharmacists being particularly lax in their dispensing habits, there have been inappropriate and/or medically unnecessary prescriptions that were routinely filled at Food City pharmacies, including hundreds of thousands of opioid prescriptions paid for by Government Programs.

240. Of note, at no time has Food City required its pharmacists to check state PDMP databases despite the evidence that using this data reduces overdose deaths, doctor shopping, and inappropriate or medically unnecessary reimbursements. This has led in many of its stores to pharmacists simply never checking state PDMP databases at all.

241. Despite filling some of the largest quantities of controlled substances of any pharmacies in the nation, Food City did little to identify, investigate, and block suspicious prescriber's prescriptions from being filled at Food City pharmacies.

242. In a 2013 article in the New England Journal of Medicine, two CVS pharmacy executives recognized that chain pharmacies are in a unique position to stop the dispensing for suspicious prescribers and outlined how data could be used. They explained that chain pharmacies "have the advantage of aggregated information on all prescriptions filled at the chain" and that "[a]nalyses of aggregated data … can also target patterns of abuse by both prescribers and patients."[184] They thus concluded that "[g]iven the growing use of controlled substances and the resulting illness and deaths, *more innovative use of transparent data is only prudent*."[185]

243. Even though the CSA required Food City to develop protocols to identify outlier prescribers and inappropriate prescriptions, there is no evidence Food City used its own easily accessible data to identify suspect doctors and medically unnecessary prescriptions.

244. Not only has it routinely ignored ongoing criminal conduct, Food City has ignored the publicly available information regarding of healthcare professionals who would lose their licenses for over-prescribing opioid drugs. For example, the Pittsburgh Post-Gazette reported that between 2011 and 2015 for Pennsylvania, Ohio, West Virginia, Maryland, Virginia, Kentucky,

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[184] Mitch Betses, R.Ph., and Troyen Brennan, M.D., M.P.H, *Abusive Prescribing of Controlled Substances—A Pharmacy View*, 369 NEJM 989-991 (Sept. 12, 2013), https://www.nejm.org/doi/10.1056/NEJMp1308222.

[185] *Id.*

and Tennessee (the bulk of Appalachia), there were 608 doctors disciplined for overprescribing narcotics.[186]

245. Thus, Food City has done little to stop its pharmacies from dispensing medically inappropriate prescriptions. In reality, Food City did the exact opposite. Instead of blocking suspicious prescribers, Food City actively courted their business and, in many areas, became the go-to pharmacy to fill pill mill doctors' prescriptions.

C. Food City Has Been Sanctioned and Paid Repeated Fines Related to Dispensing of Inappropriate Opioid Prescriptions

246. Given Food City's lack of any meaningful efforts to follow the law governing dispensing, it is unsurprising that Food City pharmacies have been sanctioned repeatedly by government authorities.

247. Food City has been sanctioned and paid repeated fines as the result of a series of investigations into its dispensing of opioids, including:

- In a June 15, 2015 press release from the Tennessee Department of Health, it was reported Food City Store No. 616 (located at 11501 Hardin Valley Rd, Knoxville, Tennessee) had been found by the Board of Pharmacy to have (a) "engaged in conduct prohibited or made unlawful" under Tennessee law or under federal law related to the practice of pharmacy and (b) with failure to comply with a "lawful order or duty promulgated by the Board." The Board fined Store No. 616 $2,000 and placed it on probation for 2 years with terms. Its Pharmacist-in-Charge was also required to provide the Board with evidence that its

[186] *See* Rich Lord, J. Bardy McCollough, Adam Smeltz, *Special Report: Overdosed – How doctors wrote the script for an epidemic,* Pittsburgh Post-Gazette (May 22, 2016), https://newsinteractive.post-gazette.com/overdosed/.

pharmacists had completed 15 hours of in-person continuing education on the dispensing of controlled substances.[187]

- That same press release reported that Food City Store No. 694 (located at 284 Morrell Road, Knoxville, Tennessee) had been found by the Board of Pharmacy to have (a) "engaged in conduct prohibited or made unlawful" under Tennessee law or under federal law related to the practice of pharmacy and (b) with failure to comply with a "lawful order or duty promulgated by the Board." The Board fined Store No. 694 $2,000 and placed it on probation for 2 years with terms. Its Pharmacist-in-Charge was also required to provide the Board with evidence that its pharmacists had completed 15 hours of in-person continuing education on the dispensing of controlled substances.[188]
- In December 2015, Food City Store No. 673 was fined $100 by the Tennessee Board of Pharmacy for violations related to its failure to comply with pharmacy security requirements.[189]
- On January 12-13, 2016, the Board of Pharmacy placed Food City Store No. 611 (located in Gatlinburg, Tennessee) on probation for 90 days and levied a $710 civil penalty.[190]
- In the August 2016 Tennessee Department of Health Disciplinary Action Report, Food City No. 674 was cited because it had "[f]ailed to adhere to rules and/or statute regarding prescriber and dispenser responsibilities; a pharmacist may compound and dispense

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[187] June 15, 2015 Tennessee Disciplinary Action Report, https://www.tn.gov/content/dam/tn/health/dar/May_2015.DAR.pdf.

[188] *Id.*

[189] January 2016 Disciplinary Action Report, https://www.tn.gov/content/dam/tn/health/dar/January.2016.DAR.pdf.

[190] *Id.*

prescription drugs and devices and related materials only in a pharmacy practice site which is duly licensed by the board and which operates in a pharmacy practice site which is duly licensed by the board and which operates in compliance with Tennessee and federal laws and rules governing the practice of pharmacy; distributed or dispensed controlled substances in violation of §53-11-308."[191] Section 53-11-308 requires that controlled substances may only be dispensed for a "medical purpose." The Board of Pharmacy ordered that Food City No. 674 would have to submit to practice monitoring by Board investigators with terms and assessed costs not to exceed $10,000.[192]

248. Food City suffered numerous similar fines and sanctions from the Virginia Board of Pharmacy at its Pennington Gap, Virginia Store No. 895, Damascus, Virginia Store No. 860, Galax, Virginia Store No. 865, Wise, Virginia Store No. 898, Big Stone Gap Store No. 891, Vansant, Virginia Store No. 839, and Bristol, Virginia Store No. 821.[193]

D. Food City Turned a Blind Eye to the Opioid Crisis

249. Food City has had knowledge and/or notice of the opioid problem since at least 2002. At any time since Food City had knowledge and/or notice of the opioid problem it could have unilaterally taken steps to curtail and prevent expansion of the problem, but it failed to do so.

250. Rather than act to curb the expansion of opioid use that Food City knew was occurring at a breathtaking pace, Food City chose not to undertake and/or failed to take action to put in place any of the measures it was capable of taking.

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[191] August 2016 Tennessee Disciplinary Action Report, https://www.tn.gov/content/dam/tn/health/dar/August.2016.DAR.pdf

[192] *Id.*

[193] Virginia Board of Pharmacy Case Decisions, https://docs.google.com/spreadsheets/d/1FcYpCJKzVOtErDpW908va7_sPlCEtDY75ng-ax5FUrw/edit#gid=0.

251. Food City was well aware of its obligations under the CSA and Georgia, Kentucky, Tennessee, and Virginia state pharmacy law and regulations to serve as a safeguard against abuse and diversion.

252. The opioid crisis and corresponding damage to Government Programs alleged herein are a direct and foreseeable result of Food City's actions and inactions. The United States and the Whistleblower States were damaged by Food City's actions.

253. In addition to measures alleged above, Food City could and should have many years ago unilaterally taken action, and/or offered a program to assist Government Programs, which had the effect of: (a) limiting to 7 days the supply of opioids dispensed for certain acute prescriptions; (b) reducing the dispensing of stronger and extended release opioids; (c) enhancing pharmacist counseling for new opioid patients; (d) limiting the daily dosage of opioids dispensed based on the strength of the opioid; and (e) requiring the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

254. Food City also failed to use data available to it to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids, or to use data available to it to do statistical analysis to prevent the filling of prescriptions that were illegally diverted, dispensed, or otherwise contributed to the opioid crisis.

255. Food City further refused to take reasonable measures to stop its retail stores from dispensing unreasonable amounts of opioids and filling suspicious prescriptions, even while telling the public it was complying with its duties as a chain pharmacy to prevent diversion. Food City did so in order to further its goal of selling as many opioids as possible and ensuring that the growing demand for opioids would be met by skyrocketing supply and an unimpeded flow of drugs into even the most suspicious pharmacies.

256. Food City knew or should have known that its pharmacies were (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling prescriptions of unusual size and frequency paid for in cash; (f) filling prescriptions of unusual size and frequency from the same prescribing physician; (g) filling prescriptions of unusual size and frequency from out-of-state physicians; and (h) filing prescriptions for patients and doctors in combinations that were indicative of abuse and diversion. The volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets.

257. Food City had complete access to, and full visibility of, all prescription opioid distribution data and dispending data related to its pharmacies throughout Georgia, Kentucky, Tennessee, and Virginia.

258. Food City had complete access to information revealing the doctors who prescribed the prescription opioids dispensed in its pharmacies throughout Georgia, Kentucky, Tennessee, and Virginia.

259. Food City had complete access to information revealing the customers who filled (or sought to fill) prescriptions for opioids in its stores throughout Georgia, Kentucky, Tennessee and Virginia.

260. Food City also failed to conduct adequate internal or external audits of its opioid sales to identify patterns regarding prescriptions that should not have been filled and to create

policies accordingly, or if it conducted such audits, it failed to take any meaningful action as a result.

261. Food City was, or should have been, fully aware that the quantity of opioids being distributed and dispensed by its pharmacies nationwide was untenable, and in many areas patently absurd; yet, it did not take meaningful action to investigate or to ensure that it was complying with its duties and obligations under the law with regard to controlled substances.

262. Food City's duties were assumed voluntarily as a condition for the privilege of selling and dispensing controlled substances throughout Georgia, Kentucky, Tennessee, and Virginia (and in this District).

263. Further, Food City has been warned (and penalized) repeatedly by governmental agencies and publicly available sources that diversion was occurring on a breathtaking scale and that the opioids supply chain fell well beneath the applicable duty of reasonable care.

264. The sheer volume of opioids sold, distributed, and dispensed throughout Georgia, Kentucky, Tennessee, and Virginia (and in this District) has been, by itself, sufficient to alert Food City that opioids were necessarily being diverted into unlawful channels.

265. Food City breached its duty to maintain effective controls against abuse and diversion of opioids, and the foreseeable result is that widespread abuse and diversion occurred.

266. Food City's breach of duty is the proximate cause and a substantial factor contributing to the damages suffered by Government Programs alleged in this Complaint.

267. The harms to Government Programs were foreseeable in light of Food City's breach of its duties.

E. Food City's Public Statements Concealed Its Failures to Prevent Filling Medically Unnecessary and Inappropriate Opioid Prescriptions

268. Food City's public statements have misled the public and officials of the United States and States to believe that it engaged in no wrongdoing and was taking proactive steps to fight the opioid epidemic and prevent fraudulent dispensing and billing.

269. For example, the Wall Street Journal featured Food City Bearden Store No. 674 in a September 19, 2019 article, noting that the store had bought nearly one million Oxycontin pills in 2008, the third highest volume of any pharmacy in the nation, prompting a "Report of Concern" from a Purdue Pharma sales representative who was concerned about the prescriptions being dispensed for patients of Dr. Frank McNiel. The article notes that Store No. 674 entered into a consent order with the Tennessee Board of Pharmacy in 2016, citing "the store for dispensing opioids and other controlled substances in a manner inconsistent with state law and regulations, including by dispensing drugs to patients who had driven long distances to the pharmacy, [] accepting postdated prescriptions, and failing to check a state prescription monitoring database before dispensing controlled substances."[194]

270. In response to the Journal article, Food City issued a statement tacitly admitting its wrongdoing, claiming that it had "refined its pharmacy practices" but had not been "accused of wrongdoing": "[T]he company has refined its pharmacy practices in consultation with drug-enforcement experts, including by not filling out-of-state prescriptions. K-VA-T hasn't been accused of wrongdoing by law enforcement, the spokeswoman said."[195]

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[194] Joseph Walker, *A Tennessee Pharmacy Bought Nearly a Million High-Dose OxyContins in 2008*, Wall Street Journal (Sept. 19, 2019).

[195] *Id.*

271. On January 24, 2020, a news story appeared in theChattanoogan.com featuring allegations made by the Tennessee Attorney General in a lawsuit against distributor AmerisourceBergen involving three Knoxville Food City pharmacies, which had been shipped 28 million opioids in a six-year period. The article reported that in January 2009 alone, Store No. 674 in Knoxville had been delivered 201,700 opiates.[196]

272. In response to questions about its opioid dispensing practices, including at its Store No. 674, Food City issued a statement again admitting there had been problems, but claiming these were nearly a decade old and touting its current commitment "to proactively working with experts in drug enforcement and pharmacy best practices to assess and refine dispensing practices at its more than 100 pharmacies....[Food City] also utilized a robust third-party review and audit program at its pharmacies. The company has been and remains committed to the safety and health of the communities it proudly serves."[197]

VII. FOOD CITY'S UNLAWFUL CONDUCT

A. Food City Violated the Controlled Substances Act

273. All DEA registrants like Food City have a duty to "provide effective controls and procedures to guard against theft and diversion of controlled substances."[198] Diversion includes the use of medication outside the usual course of professional practice.

274. The DEA has repeatedly emphasized that, as DEA registrants, retail pharmacies like Food City are required to implement systems that detect and prevent diversion and must monitor for red flags of diversion. The DEA has also repeatedly affirmed the obligations of

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[196] Roy Exum, *Opiates Scald East Ridge*, theChattanoogan.com (Jan. 24, 2020), https://www.chattanoogan.com/2020/1/24/402969/Roy-Exum-Opiates-Scald-East-Ridge.aspx.

[197] *Id.*

[198] 21 C.F.R. § 1301.71(a).

pharmacies to maintain effective controls against diversion in regulatory action after regulatory action.[199] According to DEA, pharmacists are the "[l]ast line of defense."[200]

275. The framework of state and federal statutes and regulations, along with industry guidelines, makes clear that all pharmacies like Food City possess and are expected to possess specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when dispensing of medications outside the usual course of professional practice.

276. Food City was on notice that case law and administrative proceedings interpreting the CSA clearly required that its pharmacies recognize "red flags" indicating addiction, abuse and diversion, including:

- Criminal, civil, or administrative actions pending against the prescriber[201];
- Patient's use of street slang for certain opioids (*e.g.*, "the M's" or "the Blues")[202];

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[199] *See, e.g.*, *Holiday CVS, L.L.C., d/b/a Food City/Pharmacy Nos. 219 and 5195*; 77 Fed. Reg. 62,315 (Dep't of Justice Oct. 12, 2012) (decision and order); *East Main Street Pharmacy*, 75 Fed. Reg. 66,149 (Dep't of Justice Oct. 27, 2010) (affirmance of suspension order); *Holiday CVS, L.L.C. v. Holder*, 839 F.Supp.2d 145 (D.D.C. 2012); *Townwood Pharmacy*; 63 Fed. Reg. 8,477 (Dep't of Justice Feb. 19, 1998) (revocation of registration); *Grider Drug 1 & Grider Drug 2*; 77 Fed. Reg. 44,069 (Dep't of Justice July 26, 2012) (decision and order); *The Medicine Dropper*; 76 Fed. Reg. 20,039 (Dep't of Justice April 11, 2011) (revocation of registration); *Medicine Shoppe-Jonesborough*; 73 Fed. Reg. 363 (Dep't of Justice Jan. 2, 2008) (revocation of registration).

[200] *See* Birmingham Pharmacy Diversion Awareness Conference, *DEA Perspective: Pharmaceutical Use & Abuse* (Mar. 28-29, 2015), https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2015/march_2015/prevoznik.pdf at 139-40.

[201] *Holiday CVS, LLC v. Holder*, 839 F.Supp.2d 145, 160 (D.D.C. 2012).

[202] *Id.* at 161; *Holiday CVS, LLC*, 77 Fed. Reg. at 62321, 62344 (2012).

- Cash payments: cash payments exceed national average; "unusually large" cash transactions (cash transactions average 8% or less of all transactions according to DEA)[203];
- Multiple patients with same address/last name/prescription/diagnoses/prescriber/day: (*e.g.*, all prescriptions from the same doctor have diagnoses of lower lumbar pain; code L-4, L-5, lower back pain; or severe lower back pain)[204];
- Long distance between pharmacy and prescriber (*e.g.*, Western Pennsylvania Pharmacy filling out-of-state prescriptions; 200 miles; prescribers "not from local area")[205];
- Long distance between patient and prescriber (*e.g.*, "out of state")[206];
- Long distance between pharmacy and patient (*e.g.*, southern West Virginia residence to western Pennsylvania pharmacy; 200 miles; patients "not from local area")[207];
- Prescriptions filled piecemeal over multiple visits[208];
- "Pattern Prescribing":

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[203] *Oak Hill Hometown Pharmacy v. Dhillon*, 2019 WL 5606926, at *6; *Jones Total Health Care Pharmacy*, LLC v. DEA, 881 F.3d 823, 828 (11th Cir. 2018); *Pharmacy Doctors Enterprises, Inc. v. DEA*, 2019 WL 4565481, at *5; *Holiday CVS*, 77 Fed. Reg. at 62318, 62326, 62331, 62332; DEA Affirmance of Suspension Order, East Main Street Pharmacy, 75 Fed. Reg. 66150, 66158 (2010).

[204] *Holiday CVS,* 839 F. Supp. 2d at 161; *Pharmacy Doctors Enterprises*, 2019 WL 4565481, at *5; *Holiday CVS*, 77 Fed. Reg. at 62318, 62326, 62331, 62344; *East Main Street Pharmacy*, 75 Fed. Reg. at 66159.

[205] *Oak Hill Hometown Pharmacy*, 2019 WL 5606926, at 5; *Holiday CVS*, 77 Fed. Reg. at 62321, 62332, 62333; *East Main Street Pharmacy*, DEA Affirmance of Suspension Order, 75 Fed. Reg. at 66163.

[206] *Holiday CVS*, 77 Fed. Reg. at 62318, 62322, 62326, 62335.

[207] *Oak Hill Hometown Pharmacy*, 2019 WL 5606926, at *5; *Jones Total Health Care Pharmacy, LLC v. DEA*, 881 F.3d 823, 828 (11th Cir. 2018); *Holiday CVS*, 77 Fed. Reg. at 62318, 62322, 62332, 62333; *East Main Street Pharmacy*, 75 Fed. Reg. at 66150.

[208] *Oak Hill Hometown Pharmacy*, 2019 WL 5606926, at *5.

- Prescribers writing in a "factory-like" manner, prescriptions for the same drugs, the same quantities, without any kind of variability or change considering the different patients that come into that pharmacy;
- The presence of an unwavering combination of the same drugs in the same strengths in the same quantities across numerous patients;
- Multiple patients on a single day with the same combination from a single prescriber;
- No "individualized therapy" – same prescriptions for multiple patients; maximum doses across multiple patients[209];

- High abuse potential prescriptions / "Drug Cocktails":
  - Oxycodone and Xanax;
  - Oxycodone and Alprazolam;
  - Prescriptions for both 15mg and 30 mg strengths;
  - Oxycodone, Alprazolam, and Carisoprodol
  - Prescriptions of an opiate and a benzodiazepine;
  - Oxy 30, Oxy 15, and Xanax (Alprazolam);
  - Oxy 30, Oxy 15, Alprazolam 2mg, and a fourth "filler" drug;
  - Oxy 30, Oxy 15, Xanax 2 mg, Soma, and Flexural;
  - 210 mg dose prescription of Oxy 30;
  - High quantity prescriptions;

[209] *Oak Hill Hometown Pharmacy*, 2019 WL 5606926, at 5; *Pharmacy Doctors Enterpri*ses, 2019 WL 4565481, at 5; *Holiday CVS*, 77 Fed. Reg. at 62318, 62332, 62333, 62335, 62344; *East Main Street Pharmacy*, 75 Fed. Reg. at 66150, 66157.

- Prescriptions of large volumes of controlled substances in the highest strengths;
- Multiple drugs prescribed for the same thing;
- Drugs in different classes that can cause the same side effects, like respiratory depression;
- "The Triple" or "Holy Trinity": benzodiazepine, narcotic painkiller, and sleeping pill;
- "The Homerun": benzodiazepine, narcotic painkiller, sleeping pill, and Soma;
- Multiple narcotic painkillers at the same time;
- High doses of Oxy: normal dose is 5- 10mg/4 hours;
- High doses of Xanax (alprazolam): normal dose is 4mg/day;
- High doses of Valium (diazepam): normal dose is 10mg;
- Daily dose of 300 mg of oxycodone and 60mg of hydrocodone = overdose;
- "Duplicate Therapy": multiple drugs in the same class prescribed for the same thing;
- Multiple prescriptions of same narcotic on same day;
- Multiple prescriptions of Oxycodone, Xanax, and Soma for single patient; or
- High doses of opioids in light of overdose statistics.[210]

- Patients who arrive together with identical or nearly identical prescriptions[211];

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[210] *Jones Total Health Care Pharmacy*, 881 F.3d at 828; *Pharmacy Doctors Enterprises*, 2019 WL 4565481, at *5; *Holiday CVS*, 77 Fed. Reg. at 62319, 62322, 62325, 62326, 62331, 62336, 62344; *East Main Street Pharmacy*, 75 Fed. Reg. at 66150, 66157, 66158, 66159, 66165; U.S. Centers for Disease Control, CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016, 65 Morb. And Mort. Wkly Rep. (March 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.

[211] *Pharmacy Doctors Enterprises*, 2019 WL 4565481, at *5.

- Patients seeking refills before prescriptions run out and/or patients with frequent loss of controlled substance medication[212];
- Prescription numbers are very close sequentially[213];
- Multiple out-of-area patients from the same town/area ("Sponsor Arrangements" in which people from mostly the mountain states travel in buses and vans and drive to the pharmacy to fill opioid prescriptions)[214];
- Patient's appearance/behavior (*e.g.*, appear not to need the medication, appear high, slurred speech, stumbling walk, drooling)[215];
- Prescribers without a specialty in pain management writing large quantities of prescriptions (*e.g.*, prescription influx from board certified pediatricians or gynecologists; doctors prescribing outside the scope of their usual practice; dentists; veterinarians)[216];
- Patients between the ages of 25 and 40 often paying with cash[217];
- Evidence of doctor shopping (*e.g.*, same/similar prescription prescribed by two or more prescribers at the same time)[218];
- Prescription from physician with an expired/revoked medical license, DEA number[219];

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[212] *Id.* at 5; *Holiday CVS*, 77 Fed. Reg. at 62343; *East Main Street Pharmacy*, 77 Fed. Reg. at 66157.

[213] *Holiday CVS*, 77 Fed. Reg. at 62319.

[214] *Id.* at 62319, 62331.

[215] *Id.* at 62319, 62331; *East Main Street Pharmacy*, 75 Fed. Reg. at 66151.

[216] *Holiday CVS*, 77 Fed. Reg. at 62326, 62331; *Jones Total Health Care Pharmacy*, 881 F.3d at 828.

[217] *Holiday CVS*, 77 Fed. Reg. at 62331.

[218] *Id.* at 62331, 62343.

[219] *Id.* at 62342.

- Patient prescribed only controlled substance medications[220];
- Patient presents controlled substance prescriptions under different patient names[221];
- Patient insists on brand name product or specific generic maker of opioid[222];
- Other pharmacies in the vicinity refuse to fill prescriptions from certain providers[223];
- Prescriber pattern of larger doses and higher quantities over time[224];
- Confluence of out of state patients on a single day receiving the same medications in the same quantities from the same in-state prescriber[225]; or
- The overwhelming proportion of prescriptions filled by the pharmacy is for opioids.[226]

277. It is not just the single red flags that make the suspicious prescriptions unresolvable, but frequently the fact that there are multiple red flags at one time. So, rather than just looking for unresolvable single red flags, Food City should have been looking for instances when there are multiple red flags, which would make these truly unresolvable. According to *Holiday CVS*:

> Professor Doering specifically identified such red flags as including that the patient is paying for controlled substance prescriptions with cash . . . ; the respective locations of the patient and the prescriber . . . ; that a prescriber writes for certain combinations or patterns of drugs. . . ; and multiple patients presenting "prescriptions for the same drugs, the same quantities . . . from the same doctor without any kind of variability or change considering the different patients that come into the pharmacy," thus suggesting that the physician prescribes in a

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[220] *Id.* at 62343.

[221] *Id.* at 62343.

[222] *Id.*

[223] *East Main Street Pharmacy*, 75 Fed. Reg. at 66151.

[224] *Id.* at 66159.

[225] *Holiday CVS*, 77 Fed. Reg. at 62333.

[226] *See* Birmingham Pharmacy Diversion Awareness Conference, *DEA Perspective: Pharmaceutical Use & Abuse* (Mar. 28-29, 2015), https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2015/march_2015/prevoznik.pdf at 139-40.

> ''factory like manner." *Id.* Professor Doering reviewed the various spreadsheets of the prescriptions dispensed by Respondents and testified regarding whether Respondents could have lawfully dispensed various prescriptions given the red flags they presented. For example, when questioned about CVS No. 219's dispensing of oxycodone 30 mg prescriptions, 8 which were issued by a Fort Lauderdale-based physician (P.G.) for persons whose addresses were in Kentucky and Tennessee and who paid cash, Professor Doering opined that the multiple red flags these prescriptions presented could not be resolved so that a reasonable pharmacist could dispense them consistent with his corresponding responsibility under federal law.[227]

278. Nor would Food City be able to dispense a prescription with multiple red flags by simply making a call to the prescriber. According to *Holiday CVS*:

> Doering explained that the pharmacist examines multiple red flags collectively, and testified that, in his opinion, contacting the prescribing physician and/or obtaining a diagnosis code would not resolve these red flags to a degree where the medications should have been dispensed. Tr.792–93. Doering agreed that he did not know what measures, if any, the Respondents' pharmacists took to resolve any conflicts, or whether a patient history screen was consulted prior to the dispensing event. Tr.868, 873. When pressed on whether the distance red flags were potentially explainable under various hypothetical scenarios involving vacation and travel, Doering had this to say: "The kinds of medications that we're talking about here are for chronic health problems and not acute health problems. So, it would be unlikely that someone comes to Florida on vacation, breaks a leg, and has to get oxycodone in these quantities and in these strengths. So it just doesn't add up."[228]

279. Food City was in the position to recognize those red flags listed above. All or some of those red flags were frequently present in hundreds of thousands of prescriptions its pharmacies received during the relevant time period and should have caused Food City's pharmacies to refuse to fill prescriptions and/or report the behavior. However, Food City failed to do so.

280. Food City, as a sophisticated, regional chain pharmacy, had the ability to analyze data relating to drug utilization and prescribing patterns across multiple retail stores in diverse geographic locations. Its own data would have allowed Food City to observe patterns or instances

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[227] *Holiday CVS*, 77 Fed. Reg. at 62318.

[228] *Id.* at 62334.

of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.[229]

281. Food City was on notice of what a compliance program should consist of. In 2006, the National Association of Chain Drug Stores ("NACDS"), to which Food City belongs, issued a "Model Compliance Manual" intended to "assist NACDS members" in developing their own compliance programs.[230] The Model Compliance Manual notes that a Retail Pharmacy may:

- Generate and review reports for its own purposes and refers to the assessment tools identified by CMS in its Prescription Drug Benefit Manual chapter on fraud, waste and abuse, including:
    - Drug Utilization Reports, which identify the number of prescriptions filled for a particular customer and, in particular, numbers for suspect classes of drugs such as narcotics to identify possible therapeutic abuse or illegal activity by a customer. A customer with an abnormal number of prescriptions or prescription patterns for certain drugs should be identified in reports, and the customer and his or her prescribing providers can be contacted and explanations for use can be received.
    - Prescribing Patterns by Physician Reports, which identify the number of prescriptions written by a particular provider and focus on a class or particular type of drug such as narcotics. These reports can be generated to identify possible prescriber or other fraud.
    - Geographic Zip Reports, which identify possible "doctor shopping" schemes or "script mills" by comparing the geographic location (zip code) of the patient to the location of

[229] *See, e.g., Holiday CVS*, 77 Fed. Reg. 62,315 (DEA expert witness examined dispensing records alone to identify inappropriately dispensed medications).

[230] *In Re: National Prescription Opiate Litigation,* Third Amended Complaint (Case No. 17-md-2804) (Dkt. 2613).

the provider who wrote the prescription and should include the location of the dispensing pharmacy.

282. Yet, there is no evidence Food City ever leveraged its resources and troves of information to stop or further question the overwhelming majority of prescriptions written by the criminal prescribers.

283. Food City failed to fulfill its duties as the last line of defense and failed to ensure that the prescriptions it was filling were issued to a legitimate patient for a legitimate medical purpose by a practitioner acting in the usual course of professional practice, as is evident by the copious amounts of opioids being dispensed by Food City stores throughout Georgia, Kentucky, Tennessee, and Virginia.

284. From at least 2008 to the present (and ongoing), Defendant Food City violated the CSA and Georgia, Kentucky, Tennessee, and Virginia state pharmacy laws and regulations by dispensing controlled substances in violation of the pharmacist's corresponding responsibility in violation of 21 C.F.R. § 1306.04(a) and outside the usual course of pharmacy practice in violation of 21 C.F.R. § 1306.06.

285. Food City violated the CSA and Georgia, Kentucky, Tennessee, and Virginia state pharmacy laws and regulations each time it filled a controlled substance prescription without identifying and resolving those red flags because:

- They were knowingly filled outside the usual course of professional practice and not for a legitimate medical purpose; therefore, they were not pursuant to a valid prescription under 21 U.S.C. § 829 and thereby violated 21 U.S.C. § 842(a)(1).
- They were knowingly and intentionally dispensed outside the usual course of professional pharmacy practice in violation of 21 C.F.R. 1306.06, and therefore such dispensing and

delivering of controlled substances was not authorized by the CSA, and thereby violated 21 U.S.C. § 841(a).

286. Food City failed to maintain effective controls against diversion or conduct due diligence to ensure opioids were not diverted, resulting in the gross over-dispensing of opioids. Food City thus directly contributed today's opioid epidemic and corresponding harm to Government Programs.

287. The opioid crisis described herein is a direct and foreseeable result of Food City's actions. And it was foreseeable that Government Programs would be damaged by Food City's actions.

288. Had they known that Food City dispensed scores of controlled substance prescriptions that were lacking a legitimate medical purpose and/or a medically accepted indication (and therefore did not constitute valid prescriptions under the CSA and Georgia, Kentucky, Tennessee, and Virginia state pharmacy law and regulations), Government Programs would have refused to pay for those opioid medications.

289. Below is just a representative sampling of the rampant fraud that has occurred at Food City pharmacies throughout Georgia, Kentucky, Tennessee, and Virginia.

B. Food City Failed to Investigate or Halt Dispensing of Inappropriate or Medically Unnecessary Opioid Prescriptions

290. Despite having 106 pharmacies located all over the State of Georgia, the Commonwealth of Kentucky, the State of Tennessee, and the Commonwealth of Virginia, Food City's gross inadequacies in the performance of its CSA due diligence obligations are underscored by the following examples of illegal prescribing and diversion activities in Georgia, Kentucky, Tennessee, and Virginia.

291. Upon information and belief, none of the following health care professionals (many of whose prescriptions were filled at Food City pharmacies), who were apprehended (and many of them later convicted) as a result of a DEA or local law enforcement investigation, were identified, investigated, or blocked by Food City despite their prescribing habits rising to a criminal level:

Date	Name	City	Prison
14-May-10	Stanley Naramore, MD	Cincinnti, OH	48 months
5-Aug-10	Brian Weaver, MD	Atlanta, GA	27 months
14-Aug-10	Larry Karr	Hixson, TN	108 months
9-Mar-11	Elisabeth Reimers, MD	Winchester, TN	70 months
28-Mar-11	Samuel Ashby, MD	Fayetteville, TN	108 months
12-Dec-11	Richard Albert, MD	Paintsville, KY	75 months
14-Apr-12	Allen R. Walker, MD	Portland, TN	
30-May-12	Ihsaan Al-Amin, MD	Chattanooga, TN	100 months
5-Jul-12	Michael Assevero, MD	Northlake, GA	arrested
3-Aug-12	Michael D. Leman, owner	Lexington, KY	15 years
9-Nov-12	Paul Boccone, Owner	Chantilly, VA	15 years
9-Nov-12	Charles Brown, CFNP	Chantilly, VA	5 years
18-Dec-12	Clara Rodriguez-Iznaga, MD	Plantation, FL	20 years
19-Dec-12	Hung Thien Ly, MD	Savannah, GA	97 months
14-Jan-13	Ernest William Singleton, MD	Springfield, KY	20 years
1-Feb-13	Linda Sue Cheek, MD	Dublin, VA	33 months
8-Feb-13	Larry E. Boatwright, PharmD	Germantown, TN	15 2/3 years
1-Apr-13	Thomas Patrick Brown, PharmD	Johnson City, TN	5 years
18-Apr-13	Tamral Guzman, owner	Maryville, TN	21 years
25-Apr-13	Larren Wade, MD	Alexandria, VA	70 months
4-Jun-13	Robert D. McNeese, PharmD	Greenville, TN	63 months
18-Jun-13	Gregory B. White	Georgetown, KY	2 years
15-Nov-13	Hugh Maddux, DDS	Newnan, GA	1 year, 1 month
18-Dec-13	Charles Tenhet, PharmD	London, KY	10 years
7-May-14	Randy Kincaid, owner	Maryville, TN	69 years
23-May-14	Dustin Morgan, Owner's Son	Maryville, TN	17 years
24-Jul-14	Michael Alan Patterson, MD	Bartlett, TN	16 years
1-Aug-14	Kenneth Gossett, DO	Rome, GA	42 months
1-Aug-14	Tammy Cantrell, MD	Paintsville, KY	9 years
1-Aug-14	Shelby Lackey	Paintsville, KY	97 months
1-Aug-14	Derron McRae Simon, MD	Arlington, VA	15 years
6-Aug-14	Najam Azmat, MD	Waycross, GA	11 years, 1 month

8-Aug-14	Cleveland J. Enmon, MD	Decatur, GA	20 years
19-Aug-14	Sandra Kincaid, owner	Manchester, TN	39 years
29-Aug-14	Rano Bofill, MD	Paintsville, KY	4 years
1-Sep-14	Steven Collins, MD	Roanoke County, VA	10 years
5-Sep-14	Wendi Henry, owner's daughter	Maryville, TN	18 years
10-Sep-14	Beverly Lockhart, Pharm Mgr	Pikesville, KY	72 months
16-Oct-14	David Eric Brickhouse, PA	Maryville, TN	Deceased
23-Oct-14	Robin Anne Krohn, Patient	Stafford, VA	143 months
5-Nov-14	Rosaire Michel Dubrule, MD	Tiptonville, TN	12.5 years
30-Mar-15	Ronald Hungerbuhler, DDS	Corbin, KY	1 year
1-May-15	Charles Larmore, NP	Chattanooga, TN	13 years
16-Jun-15	Charles Fred Gott, MD	Warren County, KY	8 years
26-Jun-15	Nibedita Mohanty, MD	Stafford, VA	4 years
28-Aug-15	Barbara Lang, owner	Chattanooga, TN	280 years
1-Oct-15	Faith Blake, owner	Chattanooga, TN	44 years
1-Oct-15	Jerome Sherard, MD	Chattanooga, TN	5 years
9-Oct-15	Michael Johnston, MD	Tucker, GA	10 years
27-Oct-15	Sanjay Sinha, MD	Woodstock, GA	5 years
12/9/2015	James Chapman, MD	Macon, GA	120 months
1-Feb-16	Sherry Barnett, NP	Jonesborough, TN	2 years
23-Mar-16	Gloria Faye Kennedy, FNP	Richlands, VA	46 months
24-Mar-16	Matthew Anderson, DCM	Lenoir City, TN	
24-Mar-16	David Florence, DO	Manchester, TN	
13-May-16	James Guerrero, MD	Louisville, KY	8 years
1-Jul-16	Sean P. McDonald, MD	McCracken County, KY	Probation
11-Jul-16	Alan Craig Schold	Georgetown, KY	
15-Aug-16	Bradley Lane Frost, MD	Dublin, GA	127 months
1-Oct-16	Cynthia Clemons, NP	Knoxville, TN	
4-Oct-16	Sylvia Hofstetter, owner	Knoxville, TN	
17-Nov-16	James Brian Joyner	Maryville, TN	70 months
17-Nov-16	Deborah G. Thomas, MD	Maryville, TN	10 years
13-Jan-17	Jamie Chiles Cordes, NP	Maryville, TN	54 months
21-Jan-17	Sherry Ann Fetzer, NP	Maryville, TN	3 yrs probation
21-Jan-17	Buffy Rene Kirkland, NP	Maryville, TN	2 years
1-Feb-17	Heatwole Stanley, MD	Lexington, VA	3 year probation
1-Feb-17	Stanley Elmer Heatwole, MD	Staunton, VA	3 years probation
23-Feb-17	Romie Earl Roland, MD	Atlanta, GA	10 years, 10 months
24-Feb-17	Donna Jeanne Smith, NP	Maryville, TN	2 years
4-Mar-17	Walter D. Blankenship, PA	Maryville, TN	3 yrs probation

24-Mar-17	Don Robert Lewis, PA	Maryville, TN	3 years
29-Mar-17	Nisar Piracha, MD	Atlanta, GA	7 years, 3 months
1-Apr-17	Clelia Hayes, MD	Tompkinsville, KY	1 year
4-Apr-17	Paul Spencer Ruble, DO	Brunswick, GA	5 years
24-Apr-17	Ezekiel O. Akande, MD	Somerset, KY	5 years
25-Apr-17	Edd Colbert Jones, III, MD	Fitzgerald, GA	18 months
5-Jun-17	George Kudmani	Louisville, KY	48 months
26-Jun-17	Nevorn Askari, MD	Atlanta, GA	5 1/2 years
26-Jun-17	William Richardson, MD	Atlanta, GA	4 1/2 years
30-Jun-17	Lonnie Hubbard, PharmD	Berea, KY	30 years
11-Aug-17	Clarence Scranage, MD	Fredericksburg, VA	
29-Sep-17	James Chaney, MD	Hazard, KY	180 months
15-Dec-17	Felix Eugene Shepard, MD	Norton, VA	6 months
11-Mar-18	Narendra Negareddy, MD	Jonesboro, GA	Indicted twice, murder charges
14-Mar-18	Abdeirahman Mohamed, MD	Morristown, TN	36 months
19-Mar-18	Gurcharan Kanwal	Wise, VA	Two years probation
26-Apr-18	Alan Arnold Godofsky, MD	Cincinnti, OH	5 years
7-May-18	Fred Gott, MD	Bowling Green, KY	96 months
10-Aug-18	Roy D. Reynolds, MD	Franklin, KY	50 months
29-Aug-18	Joseph Burton, MD	Alpharetta, GA	8 years
7-Nov-18	Lawrence Joseph Valdez	Hendersonville, TN	pled guilty, sentencing 4/3/2020
7-Dec-18	William Bacon, MD	Valdosta, GA	72 months
7-Dec-18	Donatus O. Mbanefo, MD	Columbus, GA	96 months
13-Dec-18	Samuel Orusa, MD	Clarksville, TN	Trial Summer 2020
7-Feb-19	Dwight Bailey, MD	Lebanon, VA	151 months
4-Apr-19	Vinod Shah, MD	Valdosta, GA	72 months
10-Apr-19	Bowdoin G. Smith, DO	Carthage, TN	
11-Apr-19	Sai Gutti, MD	Pikeville, KY	trial 2/2021
11-Apr-19	Denver Tackett, DDS	McDowell, KY	
17-Apr-19	Raymond Noschang, MD	Sycamore Township, KY	pled guilty
17-Apr-19	Timothy Abbott, DPM	Nashville, TN	Trial 3/3/2020
17-Apr-19	Brian Richey, NP	Cookeville, TN	
17-Apr-19	Daniel Seeley, NP	Batesville, MS	
17-Apr-19	Jonathan White, NP	Tullahoma, TN	
17-Apr-19	John Polston, PharmD	Tompkinsville, TN	
17-Apr-19	Charles Brooks, Jr., MD	Maryville, TN	
17-Apr-19	Henry Babenco, MD	Paducah, KY	
17-Apr-19	Sharon Naylor, NP	Jacksboro, TN	

17-Apr-19	Alicia Taylor, NP	Oneida TN	
17-Apr-19	Gregory Madron,	Jacksboro, TN	
17-Apr-19	Harrison Yang, MD	Manchester, TN	
17-Apr-19	Glenn Bonifield, PharmD	Bells, TN	
17-Apr-19	Michelle Bonifield, PharmD	Bells, TN	
18-Apr-19	Alexander Alperovich, MD	Jackson, TN	
18-Apr-19	Jeffrey Young, NP	Jackson, TN	
18-Apr-19	Andrew Rudin, MD	Jackson, TN	
18-Apr-19	Thomas Kelly Ballard, MD	Jackson, TN	
18-Apr-19	Loran Karlosky, MD	Bells, TN	
18-Apr-19	Jay Shires, MD	Bells, TN	
18-Apr-19	Charles Alston, MD	Jackson, TN	
18-Apr-19	Britney Petway, NP	Jackson, TN	
18-Apr-19	Mary Bond, NP	Bells, TN	
18-Apr-19	Richard Farmer, MD	Memphis, TN	
18-Apr-19	James Litton, NP	Memphis, TN	
19-Apr-19	Christopher Nelson, MD	Louisville, KY	indicted, trial in 2020
22-Apr-19	Steven Mynatt, MD	Knoxville, TN	Pled guilty
22-Apr-19	David G. Newman, MD	Knoxville, TN	Preparing for trial
26-Apr-19	Shriharsh L. Pole, MD	Woodbridge, VA	7 years
30-Apr-19	Curtis Edens, MD	Louisa, KY	2 years probation
13-Jun-19	Johnny Di Blasi, MD	Braselton, GA	33 months
19-Jul-19	Una Fage Ford	Appalachia, VA	
19-Jul-19	Michael B. Ford	Appalachia, VA	
29-Jul-19	Michael Lee Cummings, MD	Albany, KY	30 months
31-Jul-19	TaShawna Stokes, MD	Alpharetta, GA	guilty plea
31-Jul-19	Oscar Stokes, MD	Alpharetta, GA	guilty plea
9-Aug-19	Timothy Dennis Gowder, MD	Hixson, TN	21 years
9-Aug-19	Anwar Mithavayani, Owner	Boca Raton, FL	25 years
30-Aug-19	Pete Anthony Tyndale, Owner	Hixson, TN	29 years
11-Sep-19	Victor Hanson	Atlanta, GA	indicted
23-Sep-19	Dr. Vincent K. Jones	Martinsville, VA	indicted (deceased)
2-Oct-19	Joel Adams Smithers, MD	Martinsburg, WV	40 years
9-Oct-19	Arnita Avery-Kelly, DPM	Sandy Springs, GA	120 months
11-Oct-19	Frank H. Bynes, Jr., MD	Savannah, GA	convicted
17-Oct-19	Mohammed A.H. Mazumder, MD	Prestonburg, KY	pled guilty
18-Oct-19	Samuel Mcgaha, MD	Sevierville, TN	pled guilty
18-Oct-19	Frank McNiel, MD	Knoxville, TN	pled guilty
23-Oct-19	Heather Marks, NP	Murfreesboro, TN	Indicted

29-Oct-19	Hemal V. Mehta, MD	Brentwood, TN	indicted
2-Dec-19	Darrell R. Rinehart	Columbia, TN	Pled Guilty, sentencing 7/30/2020
8-Jan-20	Gurpreet Singh Bajwa	Oakton, VA	10 years
14-Jan-20	David Bruce Coffey, MD	Oneida, TN	Under investigation
28-Jan-20	Frank Craig Purpera, MD	Blacksburg, VA	20 months, addl sentencing on 9/24/20
26-Feb-20	Timothy Abbott, D.P.M.	Nashville, TN	Pled Guilty
27-Feb-20	John Patrick Schilling	Stockbridge, GA	indicted on 58 counts
11-Mar-20	Peter Steiner, MD	Louisville, KY	pled guilty
24-Jul-20	Raymond Michael Moore, MD	Norton, VA	Pled Guilty, 108 months
10-Aug-20	Scotty Akers, MD	Pikeville, KY	pled guilty, sentencing 11/20
17-Aug-20	Michael Grogan, MD	Crescent Springs, KY	indicted
26-Aug-20	Phillip Peterson, MD	Bluefield, VA	Pled Guilty, sentencing 12/8/20

1. ***Sevier County, Tennessee***

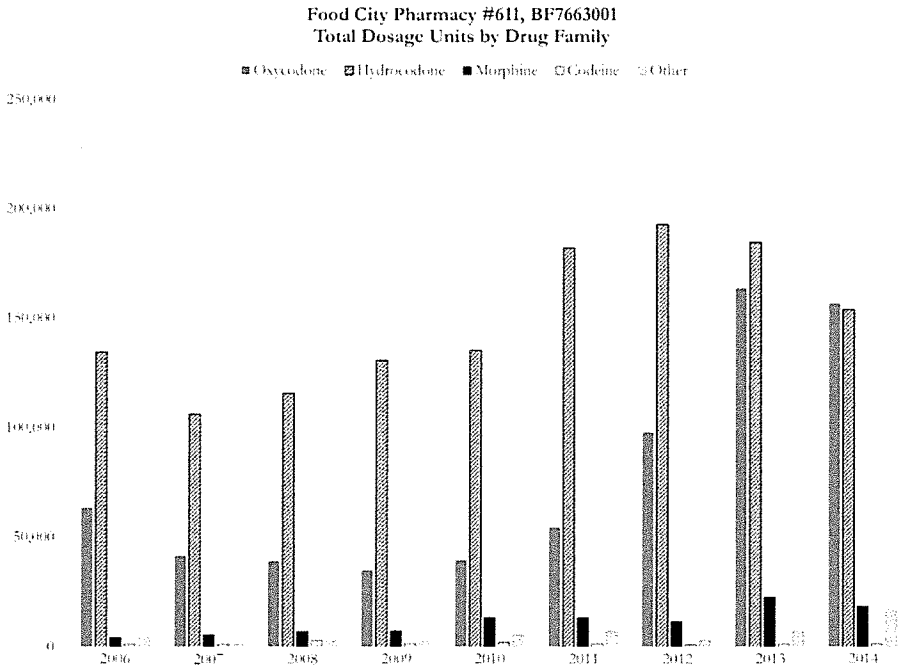
a) Gatlinburg, Tennessee (Food City No. 611)

292. Relator worked for Food City Pharmacy from March 2013 to June 2015 as a Pharmacy Technician and Pharmacy Intern. Relator worked first as a Pharmacy Technician at Store No. 687 at 2712 Loves Creek Road in Knoxville, Tennessee. He later worked as a Pharmacy Intern at Store No. 611 at 1219 E. Parkway in Gatlinburg, Tennessee. He reported to Pharmacy Manager Margo Hallman at the Gatlinburg store.

293. Food City No. 611 from 2006 to 2014 dispensed some 2,199,548 doses of opioids or 35,592,593 MME, enough at the highest bounds of the recommended MME per day (90 MME/day) for the store to supply an average of 155 opioid prescriptions per day every day for seven years.

294. According to the Washington Post, Food City No. 611 received enough opioids for 43 pills per year for each of the 5,183 men, women and children who live within five miles of this pharmacy.[231]

295. Below is a table taken from the DEA's ARCOS database depicting the glut of opioids dispensed at this Food City which saturated Gatlinburg, particularly hydrocodone:



296. After Relator graduated from pharmacy school, Food City hired him as a Pharmacy Intern at Store No. 611 in Gatlinburg. He worked at Store No. 611 while studying for his pharmacy licensing exams and the plan was for Relator to work as a pharmacist there as soon he passed the exams.

[231] Armand Emamdjomek, *et al.*, *How many pain pills went to your pharmacy?*, Washington Post (Feb. 25, 2020), https://www.washingtonpost.com/graphics/2019/investigations/pharmacies-pain-pill-map/.

297. Relator was fired by Food City purportedly after he initially did not pass his exams, which he attributes partially to the stress he was going through at Food City. (He later passed the exams without problem.) The real reason he was let go was because he had not been not shy about voicing his concerns with the way the Gatlinburg location operated.

298. When Relator started at Store No. 611, the problems were immediately evident. In Relator's experience, it would be impossible not to notice the rampant and illegal dispensing. During his time at Store No. 611, Relator felt "dirty" when he left work each day because of the blatantly illegal conduct happening at the store.

299. Store No. 611 was a very busy store, filling around 300 prescriptions per day, with at least 30-35% of the prescriptions filled for controlled substances. Many of the store's customers were from out of state. About 40-50% of Store No. 611 customers were on Government Programs.

300. Before pharmacies computerized most of their operations, they used to keep a logbook to document the dispensing of opioids and other narcotics and to track how many remaining pills were in stock at the pharmacy. The logbook at the Gatlinburg Food City Pharmacy was off by hundreds and thousands of pills.

301. Relator told pharmacy manager Hallman about that the logbook's numbers did not correlate with the actual numbers of controlled substances dispensed, but Hallman did not want to fix the logbook, so she assigned the task to her lead pharmacy technician, who was named Justin.

302. All Justin did to reconcile the book was to count how many tablets they had and then he would write that number in the book. There was no actual reconciliation. There was no attempt to ascertain how much or, more importantly, why the numbers were off.

303. When Relator would go to log a prescription, if he started to back count it, he found it would often be off by at least 700 to 800 tablets, making it impossible to reconcile.

304. The logbook issues were linked to mismanagement of the invoices Food City received from McKesson, the distributor. It was also related to not logging entries properly in the logbook. And it also might have been linked to a Food City employee stealing pills from the pharmacy. Security measures in the store were so lax that, in Relator's experience, an employee could have easily taken controlled substances out of the store without detection. Food City had such lax protocols no one would have ever noticed pills were missing.

305. Not only that, but pharmacy manager Hallman and other pharmacy staff at the Gatlinburg location never checked the Tennessee (or North Carolina) Controlled Substance Monitoring Database to verify prescriptions and ensure that they were not being filled early, nor did Food City have a policy requiring pharmacy staff to check the database.

306. The Gatlinburg pharmacy regularly filled prescriptions early on a daily basis, including for hydrocodone and oxycodone. For example, Relator recalls one customer who wanted his Xanax prescription refilled every 18 days, which the pharmacy would do.

307. He remembers another customer with a prescription for fentanyl patches that were supposed to be used for three days per patch. The prescription from the doctor had him switching the patch every 24 hours, and Food City filled the prescription for him anyway. This was a lethal dose for someone who was not addicted to opioids. The customer was a man actively working in the construction industry who did not appear to need that massive dose of fentanyl unless he was an addict or was diverting the prescriptions.

308. When Relator told his manager that he was uncomfortable filling a prescription early or filling a clearly inappropriate prescription, Hallman said, "I can't make you fill it. But I will if you won't." She then filled the prescriptions.

309. This was not an uncommon occurrence. Hallman routinely, often several times daily, filled prescriptions because Relator felt uncomfortable filling them. Even though pharmacy staff did not document instances when they filled prescriptions early, that information was clearly visible in Food City's computer system, meaning that company management should have known the Gatlinburg location was regularly filling prescriptions early. Management could easily look in the log in the computer system and see when things were filled early.

310. Manager of Pharmacy Operations Ken Slagle came into the store from time to time and was able to access the system at any time. Yet, Slagle failed to stop any of these illegal and inappropriate practices that were readily apparent to Relator who was fresh out of pharmacy school.

311. The Gatlinburg Food City pharmacy was considered a "go-to spot" for narcotics in the Knoxville area, throughout Tennessee, and even across the border in North Carolina. If addicts or drug traffickers needed a narcotic, they went to the Gatlinburg Food City.

312. The customers at the Gatlinburg pharmacy were all very familiar with pharmacy manager Hallman. They were all very friendly with her. They liked being able to get what they wanted when they wanted it. Customers who wanted prescriptions filled early always had an excuse for why they needed their medicine early: "I'm leaving on vacation"; "my grandma died"; or "I dropped it in the toilet."

313. Prior to reporting Hallman and the Gatlinburg Food City No. 611 to the Tennessee Board of Pharmacy, Relator voiced his concerns to several people, including Hallman, Justin (the lead pharmacy technician) and Food City Pharmacy Services Supervisor Tom Geoghagan that the Gatlinburg pharmacy was not keeping logbooks properly, was filling prescriptions early, or was filling inappropriate prescriptions. Geoghagan just ignored him.

314. When Relator expressed to Hallman that he was not happy with how the pharmacy filled prescriptions early, she said: "I know – they're regular customers. Sometimes they just run out."

315. Relator also spoke with Justin about filling prescriptions early and errors in the pharmacy's logbook, telling Justin: "It's illegal." Justin did not want to hear it and ignored Relator's warning.

316. Having attempted unsuccessfully to alert his managers of the issues he had witnessed, Relator reported his concerns to the Tennessee Board of Pharmacy.

317. The Gatlinburg Food City No. 611 regularly filled prescriptions from the office of Dr. Robert Maughon, whose pill mill pain clinic was located across the parking lot from Food City.

318. According to news reports, Maughon was later sentenced last year to 63 months in federal prison after he was "twice caught over-prescribing opiates and billing taxpayer-funded and private insurance to the tune of $3.5 million in an 'allergy drop' scam."[232] Maughon is the founder of First Med Inc., a chain of walk-in clinics in East Tennessee he created "despite being judged guilty by the state Board of Examiners in 1997 of over-prescribing opiates."[233]

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[232] Jamie Satterfield, *Former Gatlinburg doctor practiced 'deception' for profit, sentenced to prison in fraud*, Knox News (Jan. 25, 2019), https://www.knoxnews.com/story/news/crime/2019/01/25/robert-maughon-former-gatlinburg-doctor-sentenced-63-months-health-care-fraud-allergy-drop-scam/2666480002/.

[233] *Id.*

319. Many of Dr. Maughon's patients were Medicare beneficiaries. During the time period 2013 through 2017, Medicare Part D plans paid some $473,690 in claims for CII and CIII drugs he had prescribed, many of which were dispensed by a Food City pharmacy:[234]

DRUG	TOTAL MEDICARE CLAIMS	TOTAL MEDICARE COSTS ($)
FENTANYL	147	$33,014.31
GABAPENTIN	1,284	$32,017.46
HYDROCODONE-ACETAMINOPHEN	2,583	$59,684.01
MORPHINE SULFATE ER	347	$42,104.36
OXYCODONE HCL	1,038	$45,244.03
OXYCODONE HCL-ACETAMINOPHEN	112	$6,053.90
OXYCODONE-ACETAMINOPHEN	432	$28,875.81
OXYCONTIN	40	$33,755.86
SUBOXONE	582	$192,941.01
GRAND TOTAL	**6,565**	**$473,690.75**

320. Relator not only saw his pharmacy fill numerous inappropriate and medically unnecessary prescriptions from Dr. Maughon, he witnessed a physician's assistant from

[234] This table compiles Medicare provider utilization and payment data available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Part-D-Prescriber.

Maughon's office write himself prescriptions for narcotics that Food City pharmacy staff had already prepared for him to pick up – despite not having received a prescription for the drugs.

321. The physician's assistant came in, reached across the counter and grabbed the prescription pad, and started filling it out for the narcotics.

322. After writing himself the prescription, the physician's assistant handed it to the Food City pharmacy technician and said: "Here's the prescription you needed for the medicines you filled." The prescription was in his name as patient.

323. The physician's assistant had previously called in the prescription, and it was all ready for him. The physician's assistant then walked out of the store with eight or nine pill bottles, including hydrocodone, oxycodone, and alprazolam. After witnessing the incident, Relator once again complained to Hallman, but again nothing happened.

324. Although this was the only instance in which Relator witnessed the physician's assistant write his own prescription for drugs he was picking up, the Gatlinburg Food City regularly filled questionable prescriptions for numerous patients being treated by the physician's assistant.

325. Food City sent weekly and monthly sales update reports via email to all pharmacy staff that indicated the top-performing pharmacy locations by sales and prescription volume.

326. Manager of Pharmacy Operations Slagle and Pharmacy Services Supervisor Geoghagan also touted the performance of top-selling pharmacies during regular conference calls attended by Relator, saying: "You need to take note of how they're doing things. We need more people to be doing as good as these guys are. This is what we need as a company."

327. Executive Vice President Mickey Blazer from Food City's headquarters office in Abingdon, Virginia was occasionally on the conference calls, but they mainly included Slagle and Geoghagan.

328. After Relator became uncomfortable with the practices he was observing at Gatlinburg Food City No. 611, he told his former manager what he had seen. His former manager warned him not to go to Manager of Pharmacy Operations Slagle. Knowing that reporting internally at Food City would be a dead end, Relator went to the Board of Pharmacy directly instead.

329. Between June and September 2015, Relator spoke on numerous occasions to the Tennessee Board of Pharmacy about Food City No. 611 and Hallman. The Board and the DEA then raided the Gatlinburg store and Hallman was fired. To the best of his knowledge, Justin, the lead pharmacy technician, remained employed at the store.

330. Relator was not there when the DEA and state Board of Pharmacy raided Store No. 611, as he had been fired by Food City shortly before.

331. Larry Hill, a pharmacy investigator with the state Board of Pharmacy, later told Relator that investigators found the same issues that prompted Relator to report Hallman and the Gatlinburg Food City No. 611, including narcotic logbooks with false counts and fraudulent prescriptions.

332. In addition to being fired, Hallman was put on probation for two or three years and was not allowed to be a manager for one year. According to minutes from a January 2016 Tennessee Board of Pharmacy meeting, Hallman's license was placed on probation for one year, and she was not allowed to be "pharmacist in charge" during the probation period. She was also required to submit 15 additional continuing pharmaceutical hours in controlled substance and

recordkeeping.[235] According to the same document, the license for Food City Pharmacy's Gatlinburg store was placed on probation for 90 days, and the store was ordered to pay a $710 civil penalty for expired products.[236]

b) Sevierville, Tennessee (Food City No. 667)

333. Food City Employee No. 2 worked for Food City Pharmacy from February 2008 to December 2018 as a Pharmacy Manager and Staff Pharmacist at Store No. 667 located at 741 Dolly Parton Parkway, Sevierville, Tennessee and Store No. 611 located at 1219 E. Parkway, Gatlinburg, Tennessee. He reported to Pharmacy Services Supervisor Tom Geoghagan, who reported to Manager of Pharmacy Operations Ken Slagle.

334. Food City No. 667 from 2006 to 2014 dispensed some 2,266,705 doses of opioids or 38,831,822 MME, enough at the highest bounds of the recommended MME per day (90 MME/day) for the store to supply an average of 169 opioid prescriptions per day every day for seven years.

335. According to the Washington Post, Food City No. 667 received enough opioids for 15 pills per year for each of the 14,567 men, women and children who live within five miles of this pharmacy.[237]

336. Below is a table taken from the DEA's ARCOS database depicting the glut of opioids dispensed at this Food City which saturated Sevierville:

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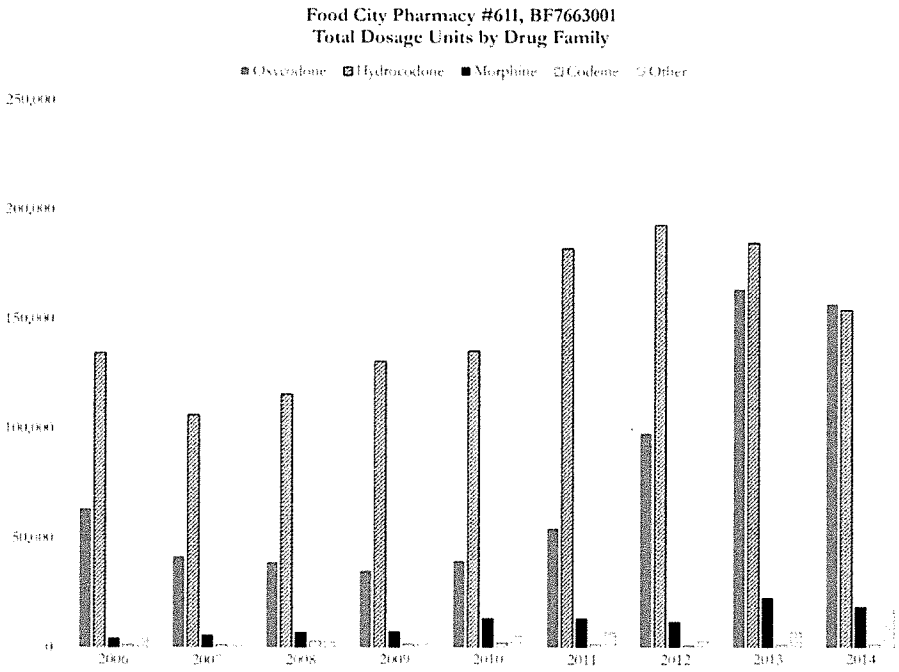
[235] Minutes, Tennessee Board of Pharmacy, Jan. 12-13-2016, at 14, https://www.tn.gov/content/dam/tn/health/documents/Mins01-16.pdf.

[236] *Id.*

[237] Armand Emamdjomek, *et al.*, *How many pain pills went to your pharmacy?*, Washington Post (Feb. 25, 2020), https://www.washingtonpost.com/graphics/2019/investigations/pharmacies-pain-pill-map/.



337. Food City Employee No. 2 joined Food City Pharmacy in February 2008 as a Staff Pharmacist at Store No. 667 in Sevierville, Tennessee. From 2010 to 2012, he served as Pharmacy Manager of the Sevierville pharmacy.

338. Pharmacy Manager Mickie Ratliff and Pharmacy Technician Allison King were arrested for stealing 1,000 or more hydrocodone pills from the Sevierville store in about 2013 after Store Manager Kevin Halcomb viewed security video of Ratliff concealing pills in her sock, Food City Employee No. 1 said.

339. Following the incident, Ratliff's license was revoked, Food City Employee No. 2 said. A January 2016 Disciplinary Action Report from the Tennessee Department of Health lists numerous violations against Ratliff, including "being addicted to the use of alcohol, narcotics or

other drugs" and "reprinted labels and paid for controlled substances without authorization from a licensed prescriber."[238]

340. Following the incident with Ratliff and King, Food City hired a security firm to review the records at the Sevierville pharmacy, Food City Employee No. 2 said. The company also installed additional security cameras at the store.

341. In addition to the incident involving Ratliff and King, Food City Employee No. 2 said that in about 2008 or 2009, a pharmacy staff member named Kylee Smith was caught stealing hydrocodone pills from the Sevierville store after pharmacy technicians noticed her "acting wobbly." Smith's license was suspended, though she was able to get it back.[239]

342. Food City Employee No. 2 said that, when pill shipments came in, he made sure to book the inventory for oxycodone pills and Schedule 2 drugs himself.

343. "As far as I was concerned, [Ratliff and King] never checked the oxycodone in – I would do it," he said. "That was just the way I preferred to do it. I would not take their word that it was there when it came in."

344. Food City Employee No. 2 did, however, allow others to book inventory for shipments of hydrocodone pills and other Schedule 3 and Schedule 4 drugs, which is likely why he did not notice any discrepancies in pill counts that would have made it apparent that someone was stealing pills.

345. "I was stupid for not coming behind and checking that the wholesaler invoice matched the book," he said, explaining that he should have compared the hydrocodone invoices

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[238] Disciplinary Action Report, Tennessee Board of Pharmacy (January 2016), at 14, https://www.tn.gov/content/dam/tn/health/dar/January.2016.DAR.pdf.

[239] March 2013 Disciplinary Action Report, https://www.tn.gov/content/dam/tn/health/dar/DAR_March_2013.pdf.

from the distributor, McKesson, against the perpetual inventory where the pharmacy had to log all controlled substances. "I don't know how they were juggling the books."

346. Food City Employee No. 2 said Food City might have had best practices regarding how to book inventory for pill shipments as they came in, but he described any such best practices as at most only "suggestions."

347. Pharmacy Services Supervisor Tom Geoghagan conducted checks of the pharmacy's perpetual inventory for controlled substances about once a month, but apparently did not catch that Ratliff and King had been stealing pills, Food City Employee No. 2 said.

348. Manager of Pharmacy Operations Ken Slagle also visited the pharmacy on occasion, primarily to ask if pharmacy staff needed anything and to inform staff about any new state guidelines, Food City Employee No. 2 said.

349. In regard to oversight of the pharmacy, Food City Employee No. 2 said local store management "stayed hands-off from the pharmacy. They didn't want to give any appearance – I'm talking about the store management locally there – you couldn't get them to come back there unless you made them or they had a problem because they didn't want to mess with the pharmacy."

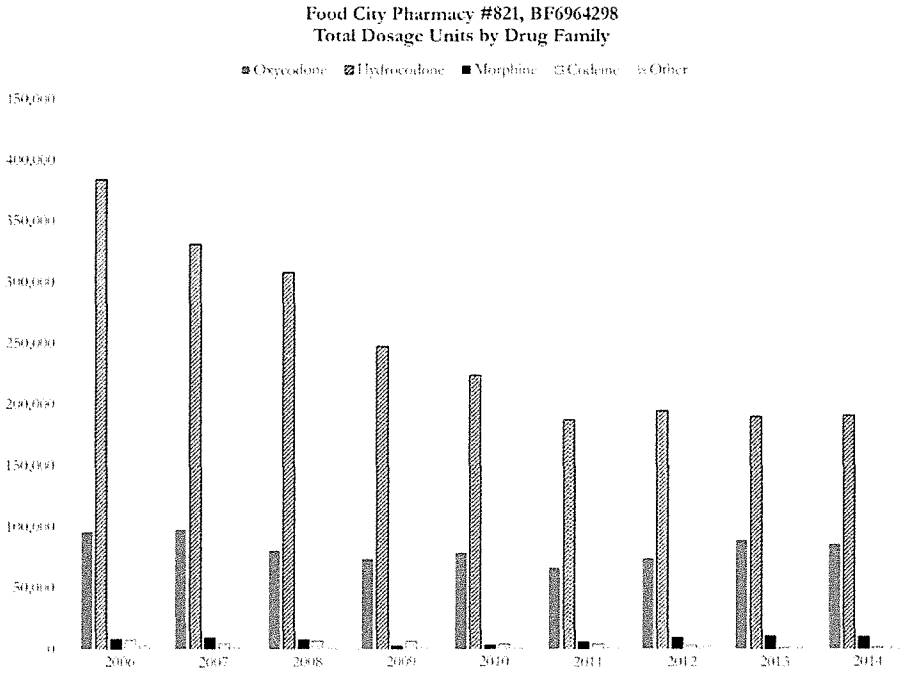
2. *Bristol, Virginia (Food City No. 821)*

350. Food City Employee No. 3 worked as a pharmacy intern for Food City Pharmacy from June 2011 to June 2014. She was based at the Bristol, Virginia location and worked at both the Bonham Road and Euclid Avenue locations there — No. 816 and No. 821, respectively— as well as other area stores on an as needed basis. While on shift, Food City Employee No. 3 worked to support the pharmacist on duty. Her technical supervisor was District Business Manager Wick Hayton.

351. According to the DEA's ARCOS database, Food City No. 821, located at 1320 Euclid Ave., Bristol, Virginia from 2006 to 2014 dispensed some 3,217,070 doses of opioids or 24,924,889 MME, enough at the highest bounds of the recommended MME per day (90 MME/day) for the store to supply an average of 108 opioid prescriptions per day every day for seven years.

352. According to the Washington Post, Food City No. 821 received enough opioids for 25 pills per year for each of the 13,231 men, women and children who live within five miles of this pharmacy.[240]

353. Below is a table taken from the ARCOS database depicting the glut of opioids dispensed at this Food City which saturated Bristol, principally hydrocodone:



[240] Armand Emamdjomek, *et al.*, *How many pain pills went to your pharmacy?*, Washington Post (Feb. 25, 2020), https://www.washingtonpost.com/graphics/2019/investigations/pharmacies-pain-pill-map/.

354. Food City Employee No. 3 started out at Food City as a licensed pharmacy technician while she was in school, going on to complete an internship there as part of her education becoming a licensed pharmacist.

355. Food City Employee No. 3 said that her district, which included stores near the state line in Tennessee and Virginia, encompassed towns like Kingsport, Tennessee, Johnson City, Tennessee, Abingdon, Virginia, Damascus, Virginia, Bristol, Virginia, and Bristol, Tennessee. The Tri-Cities area — Kingsport, Johnson City, and Bristol — was the heart of her district, Food City Employee No. 3 said.

356. Bristol is in a part of Virginia that has a lot of poverty and has been hit hard by the opioid epidemic. Many people were addicted to opioids and as a pharmacist Food City Employee No. 3 said she definitely interacted with many addicts.

357. It was not unusual for someone to seriously injure themselves to guarantee a script for a decent supply of narcotic pain medication. "To be honest with you, ER doctors are the worst [offenders]; it's not always the same doctor and they are taking the patient on their word," Food City Employee No. 3 said. "Urgent care and ER were our biggest issues — people would intentionally hurt themselves."

358. "Unfortunately, pharmacies in general have become the last red flag blower," Food City Employee No. 3 said, noting that as often as not the doctors who wrote problematic prescriptions did not want to discuss whether it was a good idea to prescribe, say, a benzodiazepine with an opioid or an inordinately large number of opioid pills. Many area doctors were "old school," and did not appreciate pharmacists using their professional discretion.

359. Food City Employee No. 3 recalled that for a while she would see dubious prescriptions from a husband and wife run establishment in Knoxville, Tennessee. "This husband

and wife couple from Knoxville, Tennessee; they eventually got busted for doing bad," Food City Employee No. 3 said.

360. Food City did not have a policy against filling those prescriptions and Food City Employee No. 3 said that she believed they typically filled them. Knoxville is hours away from Bristol, Virginia, and it was definitely unusual to travel so far to fill a prescription.

361. Asked whether the husband and wife in Knoxville, Tennessee were Dr. Janet McNiel and Dr. Frank McNiel of Bearden Healthcare Associates, Food City Employee No. 3 said that she recognized the two prescribers' names.

362. Food City Employee No. 3 did not recall learning that any physicians had been banned as a result of a complaint. She was familiar with the form filled out to kick off an investigation into a practice, but she did not know who at corporate conducted that investigation. The system made it so that complainants were anonymous, so corporate could not come back and tell the person who reported the issue how things went.

363. Then, when customers came in with scripts from the prescriber, they would tell the patient that they no longer filled for that prescriber and instruct them to call corporate for more information. That never happened while Food City Employee No. 3 was at Food City.

364. Food City Employee No. 3 said that, when she first started at Food City in 2010, one of the Virginia stores had a situation where a tech had been stealing or copying scripts and stealing medication.

365. "It was a situation where a technician was stealing opioids and stealing scripts," Food City Employee No. 3 said, noting that she did not recall at which location the incident occurred. "People started noticing and I had to go to a store I didn't work at to cover when this came down — I was asked as an intern not to alarm the individual."

366. Food City Employee No. 3 stressed that she was a very new tech at that point in time and had just started her internship. "They told me that there was things that would happen and to just do the job and focus on the job," said.

367. The individual was either copying scripts or stealing them — the same scripts were getting filled at multiple places. Opioid pills at the location had also been going missing.

368. During her time working for Food City between Marcy 2017 and December 2017, former Food City Employee No. 4 worked at Food City Store No. 821, located at 1320 Euclid Ave in Bristol. While working there, she heard from a colleague that a doctor located next to the store's parking lot "got in trouble."

369. In 2018, the Virginia Board of Medicine deemed Deborah Weddington, D.O., 1315 Euclid Ave., Bristol, Virginia to pose a "substantial danger to the public" and placed her on indefinite suspension and permanently restricted her from providing chronic pain management treatment or services.[241] The Board had previously suspended Weddington's license in 2009 and imposed a "permanent restriction on providing chronic pain management treatment." While her license was later reinstated in July 2009, she was still permanently restricted from providing chronic pain management treatment and services.[242]

370. The colleague, who was a pharmacy technician at the store, "kept commenting about people going in and out of the doctor's office, that they looked kind of homeless" and were "addicted to drugs." She also said the doctor prescribed the customers "a lot of stuff."

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[241] David McGee, *Bristol Physician Deborah Weddington Deemed Public Danger*, Bristol Herald Courier (Dec. 28, 2019), https://heraldcourier.com/news/bristol-physician-deborah-weddington-deemed-public-danger/article_4ff57130-1962-51bc-8221-b4aff182565b.html.

[242] *See* Virginia Board of Medicine Board Briefs (September 2009), http://www.dhp.virginia.gov/Medicine/newsletters/BoardBrief69.pdf.

371. In regard to customers who visited the Bristol Food City Store No. 821, Food City Employee No. 4 said she remembered colleagues saying, "'I can't believe a doctor is still prescribing them anything,'" adding that the pharmacy staff had to fill the prescriptions nonetheless because no red flags were raised when the prescriptions were entered into the computer system.

372. In regard to the Euclid Avenue store, Food City Employee No. 4 said: "That's where people who were strung out – that's where they got their stuff filled."

373. She said "you could really tell the difference" between the types of customers who visited the Euclid Avenue store compared to the customers at the Bonham Road store in Bristol. The Bonham Road store "dealt with more older people," while the Euclid Avenue store had customers in their early 20s to late 40s, some of whom were "missing teeth" and "extremely skinny," she said, adding that "you can tell they are on something."

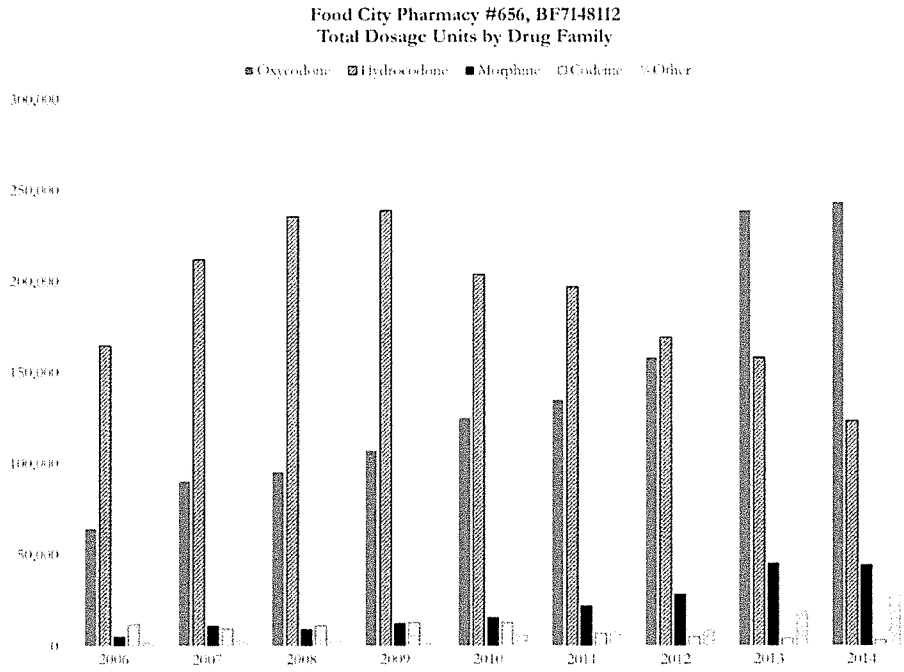
374. Pharmacy Food City Employee No. 4 said she was certain that some of these customers came to the Food City pharmacy to fill opioid prescriptions.

3. *Crossville, Tennessee (Food City No. 656)*

375. According to the DEA's ARCOS database, Food City No. 656, located at 1180 West Ave., Crossville, Tennessee from 2006 to 2014 dispensed some 3,314,425 doses of opioids or 53,373,130 MME, enough at the highest bounds of the recommended MME per day (90 MME/day) for the store to supply an average of 232 opioid prescriptions per day every day for seven years.

376. According to the Washington Post, Food City No. 656 received enough opioids for 41 pills per year for each of the 7,781 men, women and children who live within five miles of this pharmacy.[243]

377. Below is a table taken from the ARCOS database depicting the glut of opioids dispensed at this Food City which saturated Crossville:



378. Food City Employee No. 14 worked for Food City Pharmacy as a Staff Pharmacist from 2004 to 2019 at the Crossville Store No. 656. Food City Employee No. 14 said that most of the time, she was familiar with patients and the prescribing doctors. Some prescriptions came from doctors at nearby pain clinics.

[243] Armand Emamdjomek, *et al.*, *How many pain pills went to your pharmacy?*, Washington Post (Feb. 25, 2020), https://www.washingtonpost.com/graphics/2019/investigations/pharmacies-pain-pill-map/.

379. "As long as it was a local pain clinic and the clinic was still operating, I would fill [the prescriptions]," she said. "But I personally didn't want to fill for an unknown prescriber … I usually didn't."

380. Asked what happened when a customer presented a prescription from an unknown prescriber, Food City Employee No. 14 said, "Most pharmacists would probably just say, 'I'm out of [the medication]' instead of calling to verify the prescription or learning more about the patient. If the patient was familiar, that usually didn't come up. I don't know that that came up very often."

381. Food City Employee No. 14 recalled a visit by a Tennessee Board of Pharmacy inspector in 2017.

382. "I had a board inspector talk to me once about documenting – 'You've got to document, document, document,'" she said, adding that the inspector said, "'In Schedule 2 fillings, to make sure you document, document, document' … Just any notes of your observations that you went through when you were looking at the patients' file or filling the prescription."

383. "And in Food City's system, the only way to document was to type a note on the profile or prescription notes or patient notes," she said.

384. Asked if she entered notes when, for example, patients tried to fill their prescriptions too early, Food City Employee No. 14 said, "No, I didn't. I didn't leave a whole lot of notes unless it was really urgent."

385. Food City did not have a policy requiring pharmacy staff to enter notes about suspicious prescriptions or to check if there were existing notes linked to a customer's profile. "It wasn't a requirement," Food City Employee No. 14 said.

386. Asked if the pharmacy ever received suspicious prescriptions, Food City Employee No. 14 said, "Yes, there were always some that seemed questionable, but usually it was for patients that had been on the dose for a while."

387. When reviewing a "questionable" prescription – which she said usually meant "a high dose" – Food City Employee No. 14 said she typically went ahead and filled the prescription if a patient had a "satisfactory" or "reasonable" explanation.

388. "Usually I would talk to the patient first, explain that this is a really high dose, was the doctor changing your dose? Did the doctor change your therapy or something?" she said. "Get an idea of what to go by and get the patient's opinion. There could have been a circumstance or something the patient knew about that they could tell me about."

389. "If I got a satisfactory answer from the patient, or a reasonable answer, I usually would go ahead and fill it because I didn't want to interfere between the physician-patient relationship," she said.

390. Crossville also had a pain clinic in town called Advanced Spine and Pain, located at 181 Matherly St., Crossville, Tennessee. Food City No. 656 regularly filled prescriptions from the clinic, which was always crowded. The Advanced Spine doctor was Dr. David M. Arehart who specialized in anesthesiology and pain management. Arehart also has offices in Nashville and Kentucky.

391. Many of Dr. Arehart's patients, in both Tennessee and Kentucky, were Medicare beneficiaries. During the time period 2013 through 2017, Medicare Part D plans paid at least

$233,524 in claims for CII drugs he had prescribed, many of which were dispensed by a Food City pharmacy:[244]

DRUG	TOTAL MEDICARE CLAIMS	TOTAL COST ($)
ENDOCET	12	923.96
FENTANYL	158	13,729.43
HYDROCODONE-ACETAMINOPHEN	1,954	54,603.78
MORPHINE SULFATE ER	331	29,088.76
OXYCODONE HCL	73	2,611.86
OXYCODONE HCL-ACETAMINOPHEN	56	3,143.47
OXYCODONE-ACETAMINOPHEN	1,145	78,958.71
OXYCONTIN	103	48,698.61
OXYMORPHONE HCL ER	11	1,766.26
Grand Total	**3,843**	**$233,524.84**

392. According to news reports, Advanced Spine and Pain abruptly closed its doors in August of 2019 after federal prosecutors accused its management company of defrauding taxpayers by subjecting patients to unnecessary injections, drug tests and opioid prescriptions.[245]

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[244] This table compiles Medicare provider utilization and payment data available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Part-D-Prescriber.

[245] Brett Kelman and Gabe Cavallaro, *More Tennessee pain clinics shut down amid federal fraud investigation*, The Tennessean (Sept. 12, 2019), https://www.tennessean.com/story/news/health/2019/09/12/tennessee-pain-clinics-advanced-spine-and-pain-oaktree-medical-federal-fraud-investigation/2203231001/.

393. Coffey Family Medical Clinic in Oneida, Tennessee was also a part of the same company and abruptly closed in July 2020 as well.[246]

394. The South Carolina management company that operated both clinics, Oaktree Medical Centre, has also shuttered at least 10 clinics in the Carolinas as well. Federal prosecutors in South Carolina who sued Oaktree accused the company of a "series of elaborate and extensive fraud schemes" that maximized profits at the expense of patients and taxpayers. The lawsuit alleges that Oaktree and its owner, Daniel McCollum, D.C.M., used illegal kickbacks to incentivize medical professionals to overprescribe opioids and order "unreasonable" drug tests at the company laboratory, which inflated Oaktree's reimbursement from Medicare and Medicaid.[247]

395. Asked if Food City provided any training related to dispensing opioids and other controlled substances, Food City Employee No. 14 said the company "allowed each pharmacist to follow their instincts," adding, "for the most part, each pharmacist was left to their own discretion."

396. The Crossville pharmacy did not keep a list of suspicious prescribers, she said.

4. *Knoxville, Tennessee*

a) Food City No. 674 – 5941 Kingston Pike, Knoxville, Tennessee

397. Food City No. 674 received more opioids overall, both in terms of ODUs and MMEs, than any other retail pharmacy in Tennessee by a large measure. In fact, this pharmacy dispensed more opioids than almost any other retail pharmacy in the United States.

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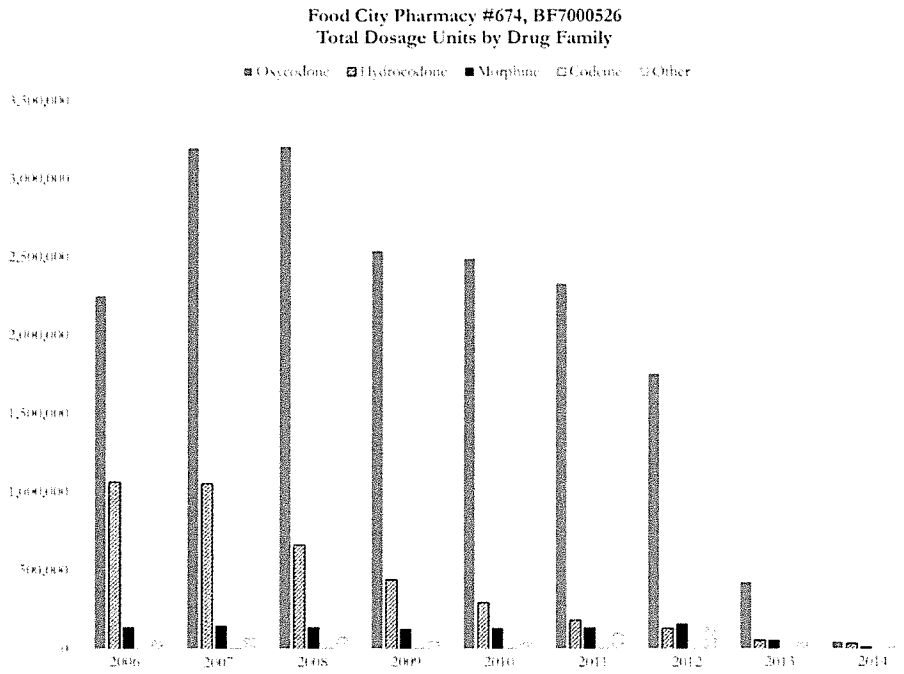
[246] *Oneida clinic at center of DEA pill mill investigation announces it is closing for good*, WBIR 10 News, July 1, 2020, https://www.wbir.com/article/news/local/oneida-doctor-under-dea-pill-mill-investigation-announces-he-is-closing-his-clinic-for-good/51-2ea9f67a-1f56-4c84-9399-84c5a8abf858.

[247] *See United States ex rel. Donna Rauch, et al. v. Oaktree Medical Centre, P.C., et al.*, Consolidated Complaint in Intervention, No. 6:15-cv-01589 (D.S.C. May 31, 2019), https://www.documentcloud.org/documents/6391657-Oaktree-Federal-Lawsuit.html.

398. Food City No. 674 from 2006 to 2014 dispensed some 23,788,408 doses of opioids or an astounding 1,009,179,696 MME, enough at the highest bounds of the recommended MME per day (90 MME/day) for the store to supply an average of 4,388 opioid prescriptions per day every day for seven years.

399. According to the Washington Post, Food City No. 674 received enough opioids for 79 pills per year for each of the 31,064 men, women and children who live within five miles of this notorious pharmacy.[248]

400. Below is a table taken from the DEA's ARCOS database depicting the glut of opioids dispensed at this Food City which saturated Knoxville, much of it oxycodone:



[248] Armand Emamdjomek, *et al.*, *How many pain pills went to your pharmacy?*, Washington Post (Feb. 25, 2020), https://www.washingtonpost.com/graphics/2019/investigations/pharmacies-pain-pill-map/.

401. Food City No. 674 was not ordering just any opioids. The pharmacy overwhelmingly ordered oxycodone, specifically high-strength OxyContin and Oxy 30, red flags in and of themselves because of their high rate of abuse and diversion.

402. Packed with up to 80 milligrams of pure oxycodone per pill, OxyContin had a street value of around $1 per milligram and quickly emerged as a magnet for abuse and diversion in the Knoxville area.

403. Likewise, generic Oxy 30 also had a relatively high street value and was even easier to abuse, particularly after OxyContin changed its formulation to make it more resistant to certain forms of abuse and diversion. Oxy 30 was an early and consistent target for abuse and diversion in Tennessee and Knoxville since it is the strongest immediate release dose of oxycodone available—especially after the reformulation of OxyContin in October 2010.

404. Food City No. 674 was located next to Bearden Healthcare Associates, Bearden Center, Knoxville, Tennessee, one of the largest and most notorious pain clinics in the state and owned by Drs. Frank and Janet McNiel. Not coincidently, the providers at this pain clinic prescribed extremely high volumes of both high dose OxyContin and Oxy 30. Even though Dr. Frank McNiel has no record of Medicare spending, his spouse Dr. Janet McNiel worked closely with her husband in the same office. During the time period 2013 through 2017, Medicare Part D plans paid some $3,851,329 in claims for CII and CIII drugs she had prescribed, many of which Food City dispensed[249]:

DRUG	TOTAL MEDICARE CLAIMS	TOTAL MEDICARE COSTS ($)

[249] This table compiles Medicare provider utilization and payment data available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Part-D-Prescriber.

DURAGESIC	12	$18,307.02
FENTANYL	199	$27,279.82
FENTANYL CITRATE	24	$55,203.15
GABAPENTIN	1,118	$17,387.67
HYDROCODONE-ACETAMINOPHEN	761	$33,811.83
HYDROMORPHONE HCL	278	$14,946.46
MORPHINE SULFATE	72	$2,335.13
MORPHINE SULFATE ER	907	$101,655.93
MS CONTIN	117	$139,328.08
OPANA ER	1,319	$903,871.48
OXYCODONE HCL	3,604	$197,623.61
OXYCODONE HCL-ACETAMINOPHEN	80	$3,326.36
OXYCODONE-ACETAMINOPHEN	211	$11,215.78
OXYCONTIN	1,507	$1,201,787.66
OXYMORPHONE HCL ER	1,095	$416,748.35
SUBSYS	39	$393,289.69
XYREM	47	$313,211.06
GRAND TOTAL	**11,390**	**$3,851,329.08**

405. Food City No. 674 captured the bulk of the oxycodone prescriptions from Bearden Healthcare Associates even though there was a Walgreens and a CVS which dispensed controlled substances and are located literally yards away across the street from Food City No. 674. Food

City would honor prescriptions from Bearden Healthcare Associates that others, such as Wal-Mart, Walgreens, and CVS, would not.

406. Red flags abounded at Food City No. 674.

407. The family of Gerald Armstrong sued Food City and Bearden Healthcare Associates after Mr. Armstrong died of an overdose from OxyContin. According to court documents, between 2002 and 2005 Bearden Healthcare Associates clinic providers prescribed him more than 20 different controlled substances, including OxyContin, Diazepam, Xanax, and Paxil—all of which Food City No. 674 filled.

408. A patient's son posted a complaint about Dr. McNiel on October 27, 2010 claiming that they were:

> killing him with all the medicine they presribed him heres a list 360 oxycontin 80mg, 180 oxycontin 60mg, 360 hydrocodone 10mg, 240 xanax 10 mg and neurontin. And they did this for 7 years. The thing that bothers me is that he was never offered treatment to ween him off this is very dangerous. I only wished they would have done this sooner because now we (his family) are dealing with a 76 year old addict. I hope nobody else has to deal with this and they close this doctors office down and take Dr. Franks license before he kills somebody if he hasn't already!!![250]

409. A news article reported that Christina Collins, a nurse practitioner at the clinic, had prescribed enormous quantities of opioids, including for one patient 32 tablets of methadone to be swallowed eight times a day. The same patient was then "instructed to take two Roxicodone, another opioid, four times a day. Then a tablet of Soma, a potent muscle relaxer, four times a day. Six Xanax were sprinkled in between."[251]

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[250] Yp: The Real Yellow Pages, https://www.yellowpages.com/knoxville-tn/mip/bearden-health-care-associates-467684475.

[251] Brett Kelman, *This pain clinic nurse gave a patient 51 pills a day. And she kept her license*, Tennessean.com (Oct. 11, 2018), https://www.tennessean.com/story/news/2018/10/11/opioid-epidemic-tennessee-pill-mills-christina-collins/1488026002/.

410. The Tennessee Department of Health has concluded that Collins' "contributions to the epidemic are 'obvious and appalling' and that her prescriptions were 'so colossal' that their only reasonable use would be drug trafficking or suicide."[252]

411. The clinic strongly recommended Food City Store No. 674 in particular, not because of its close proximity, but because it was one of the few pharmacies that would fill a prescription.

412. Not surprisingly, the incredible volume of opioids dispensed at Store No. 674 attracted considerable criminal activity. On September 8, 2007, an elderly woman was sprayed in the face with mace and had her prescriptions stolen as she was leaving Food City No. 674. Less than a week later, another patient was robbed at gun point in the Food City No. 674 parking lot for his controlled substance prescriptions.

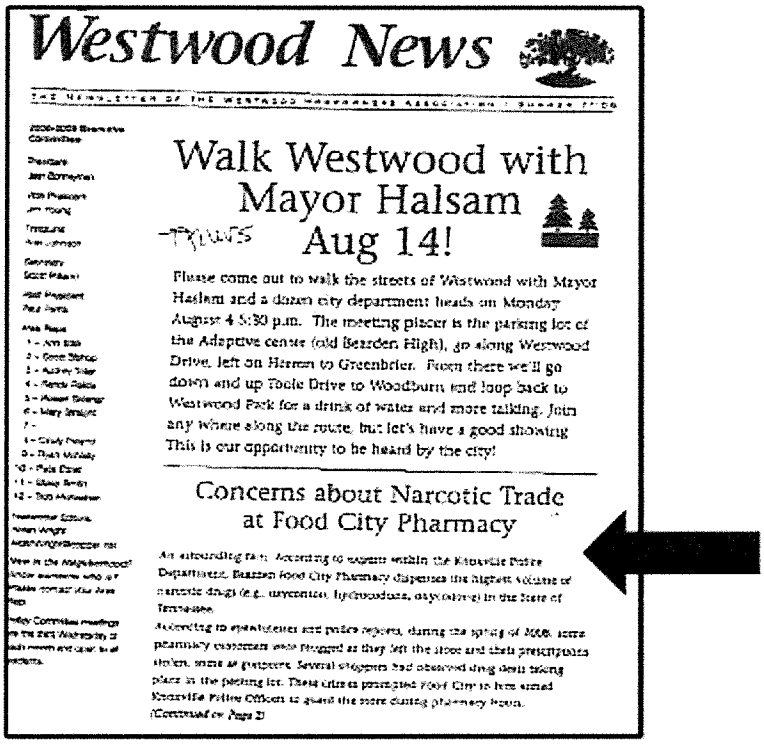
413. In fact, it became increasingly common for criminals to wait in the store's parking lot and then follow patients home to rob them of their prescriptions. Incidents like this eventually led Food City to hire armed off-duty police officers as security during pharmacy hours.

414. Around the same time, residents of Bearden, which is in an affluent area of Knoxville, noticed the high volume of traffic coming in and out of the Bearden Healthcare Associates and Pharmacy No. 674, many with plates from counties all over the state and from other states.

415. Aside from the high numbers of opioids being dispensed, there were credible reports that rampant diversion was occurring at Food City No. 674. In the summer of 2008, Westwood News, the newsletter of the Westwood Homeowners Association, which was next door

[252] *Id.*

to Food City No. 674, published a story titled "Concerns about Narcotic Trade at Food City Pharmacy" regarding Food City No. 674 and the Bearden Healthcare Associates:



Westwood News

Walk Westwood with Mayor Halsam Aug 14!

Please come out to walk the streets of Westwood with Mayor Haslam and a dozen city department heads on Monday August 4 5:30 p.m. The meeting place is the parking lot of the Adaptive center (old Bearden High), go along Westwood Drive, left on Harmon to Greenbrier. From there we'll go down and up Toole Drive to Woodburn and loop back to Westwood Park for a drink of water and more talking. Join any where along the route, but let's have a good showing. This is our opportunity to be heard by the city!

Concerns about Narcotic Trade at Food City Pharmacy

416. The article stated:

An astounding fact: According to experts within the Knoxville Police Department, Bearden Food City Pharmacy dispenses the highest volume of narcotic drugs (e.g. oxycontin, hydrocodone, oxycodone) in the State of Tennessee. According to eye witnesses and police reports, during the spring of 2008, some pharmacy customers were mugged as they left the store and their prescriptions stolen, some at gunpoint. Several shoppers had observed drug deals taking place in the parking lot. These crimes prompted Food City to hire armed Knoxville Police Officers to guard the store during pharmacy hours. Just around the corner from Food City, at 420 Bearden Road, is Bearden Healthcare Associates, a clinic operated by Drs. Frank and Janet McNiel. According to one local Drug Enforcement Agency [sic] (DEA) official, this clinic, when it comes to overprescribing narcotics, is "the biggest problem in the state."

According to Knoxville Police and the DEA, Bearden Food City Pharmacy was the only pharmacy in town still accepting prescriptions from the Drs. McNiel. A group of concerned neighbors began meeting to address the issue. Their goal was to

> persuade Food City to put neighbors first and stop honoring the Drs. McNiel's narcotic prescriptions at any of the Knoxville Food City pharmacies[.]

417. Food City's dispensing of oxycodone at Store No. 674 was heavily disproportionate even amongst its own stores. Combined with Food City Nos. 616 and 694, the three pharmacies dispensed over 1.1 million doses of Oxy 30 in just four months.

418. Dr. Frank McNiel practiced medicine for 33 years in Tennessee, including 19 at Healthcare Associates in Knoxville. He ranked as one of the top pain pill prescribers in the nation, and accounted for one out of five opioid products prescribed in the Knoxville area.[253]

419. It was well known that McNiel's patients were abusing and/or diverting their opioid prescriptions. For example, Ann Evamay Noor, a resident of Piney Flats, Tennessee, pled guilty on October 24, 2011 to illegally selling and distributing prescription narcotics.[254] Noor had on a monthly basis received prescriptions for oxycodone (including OxyContin), fentanyl and diazepam from Dr. McNiel. After she sold prescription pills to an undercover informant, more than $10,000 cash was seized from her home during the execution of a federal search warrant in September 2010.

420. Pharmacy records confirmed that in July 2010 alone, Dr. McNiel had prescribed Noor 450 oxycodone 30 mg tablets; 240 OxyContin 80 mg tablets; 90 fentanyl transdermal patches; 360 diazepam 10 mg tablets; and 600 carisoprodol 350 mg tablets.[255]

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[253] *East TN Docs to Plead Guilty to Pill Dealing*, www.tnoverdoseprevention.org, Sept. 9, 2019, https://www.tnoverdoseprevention.org/single-post/2019/09/26/East-TN-Docs-to-Plead-Guilty-to-Pill-Dealing?_amp_.

[254] Plea Agreement, *United States v. Ann Evamay Noor,* 2:11-CR-61 (Oct. 24, 2011).

[255] *Physician's wife sentenced for selling pain pills*, Knoxville News Sentinel (June 14, 2012), http://archive.knoxnews.com/news/state/physicians-wife-sentenced-for-selling-pain-pills-ep-360520037-356939181.html/.

421. At Noor's sentencing hearing, U.S. District Judge Ronnie Greer cited statistics from the CDC showing that overdose deaths outnumber traffic fatalities and told Noor "[y]ou are not alone.... The doctors who over-prescribe these drugs are complicit in these crimes and are complicit in these statistics."[256]

422. Dr. McNiel had been subject to professional discipline from the Tennessee Board of Medical Examiners for overprescribing from as far back as 1994.[257] Until 2012, McNiel owned and managed the Bearden Healthcare Associates, after which he ran a pain clinic out of his home.

423. According to the United States' Sentencing Memorandum, Dr. McNiel at no time checked the Tennessee Controlled Substance Monitoring Database ("CSMD"), nor did he order urine screens to ensure patients were not putting their lives at risk by mixing the medications they were taking in deadly combinations. Dr. McNiel prescribed the "Holy Trinity" to multiple patients. From 2015 to the surrender of his medical license in 2017, Dr. McNiel prescribed MME levels ranging from 150 to 2457 (*i.e.*, anywhere from 67% to 2630% above what the CDC recommends). From his home practice, he prescribed approximately 60,000 controlled substances from 2012 to 2017 and approximately 20,000 controlled substances from 2015-2017. There is no evidence that he used urine drug screens or checked the CSMD for any of these prescriptions.[258]

424. Dr. McNiel was forced to surrender his medical license permanently in March of 2018 after the Tennessee Board of Medical Examiners found that, from 2002 until 2018, Dr. McNiel had "prescribed opioids and other controlled substances in amounts and/or for durations

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[256] *Id.*

[257] Sentencing Memorandum, *United States v. Frank McNiel*, No. 3:19-CR-170 (Mar. 12, 2020), at 1.

[258] *Id.*

not medically necessary, advisable or justified for a diagnosed condition and/or not for legitimate medical purpose; without attempting alternative non-narcotic modalities; and without appropriately monitoring for abuse and diversion."[259] The Board also found that he improperly supervised his nurses and physician's assistants "who continued such excessive prescribing of opioids [in] excessive amounts."[260] Dr. McNiel was arrested and pled guilty to a federal charge of unlawful distribution in October 2019.[261]

425. Food City Employee No. 15 worked for Food City Pharmacy as Director of Pharmacy from 1999 to 2004 out of Food City's corporate headquarters office in Abingdon, Virginia. He also visited many of the company's pharmacy locations throughout Virginia, Tennessee and Kentucky.

426. The pharmacy at Store No. 674 in Knoxville was doing about 44% to 46% of its business from CII prescriptions, an abnormally high amount, Food City Employee No. 15 recalls. Many of the CII prescriptions were from the nearby pain clinic – the one run by Bearden Healthcare Associates.

427. "When everybody's getting Xanax, Lortab, Percocet, it's not hard to figure out," he explained. "Every three to six months it seemed like there was a new doctor coming and going [from the clinic]."

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[259] *See* Minutes, Tennessee Board of Medical Examiners, Regular Board Meeting, March 20=21, 2018, https://www.tn.gov/content/dam/tn/health/healthprofboards/minutes/me/ME032018.pdf.

[260] *Id.*

[261] Press Release, *Two East Tennessee Doctors Plead Guilty to Opioid Offenses*, Department of Justice, Oct. 18, 2019, https://www.justice.gov/opa/pr/two-east-tennessee-doctors-plead-guilty-opioid-offenses.

428. Food City Employee No. 15 said he addressed the issues he saw at pharmacy No. 674 with Food City President and Chief Executive Officer Steve Smith. "I talked to him a lot about some of the stores we had that I thought were problematic," Food City Employee No. 15 said.

429. In regard to Store No. 674 in Knoxville, Food City Employee No. 15 told Smith "this is going to throw up a lot of red flags. When the state drug inspectors look at this, … [they will see] we were doing a highly unusual percentage of CII drugs."

430. Food City Employee No. 15 told President and CEO Steve Smith that the company needed to try to build the pharmacy business with prescriptions other than CIIs. Smith replied that they would continue to fill CIIs because the prescriptions were written by licensed physicians: "'That's fine. They've got a doctor's license; they're putting them out.'"

431. "[CEO Smith] said his bottom line was to 'increase sales, increase business and increase prescriptions,'" Food City Employee No. 15 said. "It was mostly about sales with him. I kept telling him, I said, 'Sales will come. We need to concentrate on filing legitimate prescriptions and building our prescription base with doctors.' He wanted more dollars."

432. Food City Employee No. 16 was an uncertified pharmacy technician at the Food City Store No. 674 from 2007 to 2010. Her bosses were pharmacists Julie Vardy (who was also the pharmacy manager) and Deanna Register. She left the job to go to graduate school out of state.

433. She also worked 20 hours a week at the Food City pharmacy at 9565 Middlebrook Pike in Knoxville (Store No. 672) for six months in 2015 and sometimes filled in at other local Food Cities that were short a pharmacy tech, but only for a day or two at a time.

434. Her job responsibilities included filling prescriptions, putting prescriptions into the computer system; filing them because they have to keep prescriptions for seven years, counting up

the medicine, labeling the bottles, talking to the doctor's offices when there was an issue with a prescription, dealing with customers and answering the phone.

435. However, she was also allowed to fill prescriptions for opioids, because of the volume of business the pharmacy No. 674 did, which is usually something only a pharmacist can do.

436. But Food City Employee No. 16 said that simply was not possible at Food City No. 674. "At a normal pharmacy, yes, absolutely, the pharmacist can be the only one who touches CIIs," she said. "But we did such volume there's no way you could run that pharmacy without the techs filling them," she said. "We had at least three techs in there every day, sometimes four or five, and still we were so busy every single day. It was nonstop."

437. The pace was intense, so intense that most days she and the other techs did not get to take the two 15-minute breaks they were entitled to, and she said she only got to take a lunch break because state law mandated that.

438. Food City Employee No. 16 said she filled hundreds of prescriptions a day for "thousands" of opioids and that 90 percent of the prescriptions they filled were opioids, which was unusual, and 80 to 90 percent of their total business came from patients of pain specialists, mostly from nearby Bearden Healthcare Associates.

439. For instance, when she worked at Food City's Store No. 672 she filled maybe 20 CII prescriptions during the six months she was there and that includes hydrocodone because by then it was a CII, she said.

440. Store No. 674 had CII deliveries every day, "which is unheard of," she recalled. "We had all the strengths of oxycodone, of Oxycontin, different brands of everything," she said. "We had fentanyl. We had drugs that I've never seen in another pharmacy – like hydromorphone.

I've worked at two of the Food City locations and then I've worked at several more of them for a few days if they needed help and some of those drugs I've never seen at another pharmacy."

441. They would get a couple of boxes of fentanyl patches and 20 or 30 bottles of oxycodone 30s, which have 100 per bottle and are what they sold the most of, and 'just whatever you've run out of the day before," she said.

442. "They'd send them in these big plastic containers with the lids that lock together – a tote," she said. "We'd get one of those a day."

443. One patient could get as many as 360 pills at a time, Food City Employee No. 16 said. "The doctors put them on extended release medications, but 30s are immediate release, so you give them for breakthrough pain so usually patients get both, but different brands," she said.

444. The norm for most pharmacies is to "not have very much" controlled substances on site, she said, adding: "A normal pharmacy will have some Percocets and some low dosage oxycodone and probably anything else they'll have to order. If you have a regular patient that needs it you'll keep it in stock, but most pharmacies will have one little safe where all their CIIs are. And [at Store No. 674] we had two big safes and two medium safes."

445. At Store No. 674, the pharmacy had four safes to store the CIIs – two the size of a refrigerator and two medium sized ones the size of a 32 to 40-inch console TV. The two large safes, one was grey, and one was green, were in the back of the pharmacy, she said. One of them the pharmacists had to open the safes. The other safe was kept closed, but the techs knew the combination to open it.

446. "They were for things that didn't move quickly – all the ADHD drugs and all of the fentanyl was in there," according to Food City Employee No. 16. "Fentanyl comes in big packages so it wouldn't fit in the smaller ones."

447. The two medium-sized safes were under the counters, one in the front and one in the back, and were unlocked. They kept the CIIs that were the "fast movers" – oxycodone, Oxycontin, morphine, Percocet – in the medium-sized safes, she said. During the time Food City Employee No. 16 worked at Store No. 674, "[w]e locked them every night before we left, but they were unlocked when we were there because we were in there constantly."

448. Seventy-five percent of the customers were "regular customers you see every month," she said. "The thing is not a lot of pharmacies carry a lot of CII's so we would get people they sent to us because they knew we had those medications in stock," Employee No. 16 said, adding this led to problems: "Which is a problem because you don't know the doctors. You'd get people who would call you and say, 'Do you have 30 milligram MS Contin, which is the brand name for morphine, in stock? I'm like, 'Who are you?' Some people just had to have the brand name for reasons I can't understand. I always felt those people may not be totally legit, but maybe there's a dye in the generic they're allergic to."

449. Food City Employee No. 16 said she was concerned so many patients wanted the brand Oxycontin: "This always made me uneasy. Some people would say that need the brand name of Oxycontin. Why? There's not that big a difference in ingredients between that and the generic. And if for some reason you had to change the prescription because the doctor gave them too much, well, people threatened my life at that job."

450. She said it was "pretty common knowledge" around Knoxville that if you needed CII's, you went to Store No. 674. The store got deliveries of opioids every day, which made it a target for criminals, so the store hired two off-duty police officers to work there.

451. "They walked us to and from our cars and they made sure nobody got out of hand," Food City Employee No. 16 said. "I saw them tase a guy once. He was throwing a fit and the store

manager came out to talk to him and he started getting physical, so the cop got in between them and tased him. He knocked over a whole display of pet food."

452. The police were necessary, Food City Employee No. 16 said. "I did have that one guy threaten my life and there were some people who would really get hostile," she said. "They were making sure we didn't get hurt and they were making sure no drug deals went down in the parking lot and that the patients could get to their cars without somebody holding them up."

453. While Food City Employee No. 16 was never robbed during her time at Store No. 674, some patients were mugged for their drugs in the parking lot. Sometimes the police would stand near the pharmacy or sometimes inside the pharmacy, but sometimes they would watch the front of the store for suspicious behavior, she said.

454. When Food City Employee No. 16 first started working at the pharmacy, she "did not know they did such a high volume of narcotics. I'd never worked at a pharmacy before I got this job so for a while I thought that's how all pharmacies were."

455. Many of the Bearden Healthcare Associates' patients were from Kentucky, Food City Employee No. 16 said, but the fact that patients had driven such long distances did not arouse their suspicions. "I guess it's hard to get into a pain clinic and find one that's doing things correctly," she said.

456. The Bearden Health Associates' patients who got opioid prescriptions filled with Store No. 674 every month had "pain contracts" signed by the patient, the doctors at the clinic and the pharmacist, she said. The pain contracts "outlined all of the rules of patient conduct," she said. The contracts spelled out that "[y]ou cannot get controlled substances from any other source, etc. The patient signs this and a copy is held at the doctor office and the pharmacy and given to the patient. If for any reason it's violated, they were fired by the doctor's office."

457. Part of the pain contract was "they had to get all of their controlled substance medication via Dr. Frank or whoever they were seeing at the Bearden Healthcare Associates," Food City Employee No. 16 said. "So, if they had a psychiatric illness and they needed ADHD meds it also had to come from Dr. Frank so that way he was keeping an eye on what the interactions could be."

458. They would not fill prescriptions for opioids from regular (*i.e.*, monthly) customers who did not have a pain contract, she said. "Everybody we saw who got pain medication regularly was on contract," she said.

459. She did not question the volume of opioids being dispensed. "I'm not the doctor and I'm not the pharmacist," Food City Employee No. 16 said. "A lot of the patients are dying of cancer or have a horrific injury. The diagnosis usually made sense with the amount of medication they were getting."

460. The doctor determined the patient's pain level, which the doctor factored in when writing the prescription, she added.

461. About five percent of the pain contract patients were from out of state, mainly Kentucky; about 50 percent were from the Knoxville area and the rest were from further away in Tennessee.

462. "I don't know why they chose to go to an out of state pain clinic" or one far from where they lived, Food City Employee No. 16 said. "I do know at that time pain clinics were under a lot of scrutiny so maybe there wasn't somewhere legitimate around where they lived."

463. The pharmacy had a list of doctors whose prescriptions they would not fill and a list of patients that, "for whatever reason, we were uncomfortable filling for," she explained. They

had a paper list for each as well as keeping it in the computer "so if you didn't know and went into the computer you could see, 'Nope, you couldn't do it,'" she added.

464. They had to turn them away patients "a few times a month and it was usually people who [were from] out of state or people who were double dipping, people we hadn't seen before," Food City Employee No. 16 said. "It was usually not regular patients from the pain clinic next door [Bearden Healthcare Associates], but sometimes we did. Sometimes we'd pull up the database and find out this established patient had been getting paid meds from somewhere else or doing something shady."

465. They did not routinely check the PDMP databases for the regular patients that came monthly, but if it was a first-time patient with a pain contract, '[y]ou go over the pain contract, you check the database to make sure they're not getting controlled substance meds anywhere else and the pharmacist would spend a long time talking to them while checking them out, saying, 'These are the things that can happen with these medications. These are the things you should not do with these medications,'" she said.

466. Between 20 and 30 percent of the pain contract patients paid in cash, Food City Employee No. 16 said, which was "kind of scary for me. For one thing, if they don't have insurance, the insurance company has their own internal system for checking if a prescription was filled before."

467. And some customers came in with "a lot" of cash, as much as $2000, "for whatever reason," and "that always made me nervous," she said. "I understand kind of because a lot of these pain patients could not work with their disabilities, but it always made me really uncomfortable."

468. As a pharmacy technician, Food City Employee No. 16 was evaluated on how she interacted with customers and if she filled prescriptions correctly. However, store managers "got

a bonus having to do with how much money the pharmacies make," she said. "I don't really know much more about that because it didn't affect me personally."

469. Food City Employee No. 5 worked as a pharmacist for Food City Pharmacy from 2006 to 2010. Food City Employee No. 5 was a floater pharmacist for Food City, working at stores all over east Tennessee, including No. 674, an extremely high-volume opioid dispensing pharmacy, in the Bearden Shopping Center. He worked as a floater there on a couple occasions and it was clear they were dispensing a staggering quantity of narcotic pain pills.

470. Dr. Janet McNiel and Dr. Frank McNiel, the owners of the nearby Bearden Healthcare Associates, had written the vast majority of the opioid scripts Food City Store No. 674 was filling. Store No. 674 primarily dispensed opioids on the occasions when Food City Employee No. 5 worked there.

471. The company was constantly looking for pharmacists to work at Store No. 674 and the vast majority did not want to. It was common knowledge that Doctor McNiel had a troubled history of investigations in the state, Food City Employee No. 5 said.

472. "I was a fill-in pharmacist, so I was often working with another pharmacist, who may or may not have been a PIC there," Food City Employee No. 5 said. "There was a lot of fluctuation there; it was a high volume prescription store for them and burnout in retail pharmacy can be significant; they went through several PICs in those four years, so there were a lot of different pharmacists there."

473. Most of the time Store No. 674 had at least three pharmacists on duty to handle the volume of opioid prescriptions and still counsel the patients, most of whom were receiving high strength, high pill-quantity orders.

474. "We were trying to have at least three pharmacists there, just to handle the volume and try to do as much counseling as we possibly could," Food City Employee No. 5 said.

475. "A lot of times they were just too busy [for counseling]; they usually had a dedicated pharmacy technician for input and at least two normal technicians, and then two fill technicians, then a pharmacist that took care of the controlled substance log — at the time we did a perpetual inventory of the CIIs — there was a pharmacist usually dedicated to doing the due diligence, writing up the prescriptions and doing the accounts and making sure that the accounts were correct."

476. It was unusual to have a dedicated pharmacist taking care of the perpetual CII log, but Food City No. 674 was so busy that the task demanded full-time attention.

477. About a year before he left the company, Food City Employee No. 5 was offered a pharmacist-in-charge position at the notorious Food City No. 674. He wrote a letter to the relevant parties at the company, explaining that he felt they needed to divide the load of the location between two pharmacies or assign a designated pharmacist to go work from Bearden Healthcare Associates, where they could conduct appropriate due diligence for the number, quantity, and indication of the scripts.

478. "The due diligence we have to have is the same now as then," Food City Employee No. 5 said. "There's a corresponding responsibility that we have [as a pharmacy]."

479. Food City Employee No. 5 did not ever learn what his superiors at Food City thought of his ideas because he never heard back on the PIC position at No. 674 again. However, his relationship with his employer seemed to have soured after that, and he left the company about a year later. Food City Employee No. 5 said he had a feeling the Bearden Healthcare Associates

doctors and nurse practitioners did not want a pharmacist setting up shop in their clinic and questioning their prescribing practices.

480. Food City Employee No. 5 said it seemed like Food City management felt was criticizing the way they were operating Store No. 674's pharmacy. The company did not seem to see the problems that made the store such an undesirable place to work for pharmacists, who risk their professional licenses when dispensing controlled substances.

481. "At [No. 674], they had a dispensing robot counter that counted out the pills, and most of [the opioid] tablets were in that," Food City Employee No. 5 said. After the robot dispensed the medication for a patient, a technician counted the pills; then, a pharmacist typically counted the pills again.

482. "I don't remember a company-wide policy [for responding to red flags]. Food City really relied on the pharmacist to make the judgment," Food City Employee No. 5 said. "When I was offered that position, I wanted more interaction with [the Bearden Clinic], I wanted to be allowed to do adequate due diligence, not be forced to fill."

483. Food City Employee No. 5 said he was offered the position at No. 674 at a time when it was becoming very clear Tennessee had an opioid problem. At many other stores where Food City Employee No. 5 worked, "we had a lot of prescriptions from out of state; if you filled one for a local who went to Florida, Alabama, Georgia, you fill one then get seven in the next hour."

484. Asked how word spread so quickly through the underground opioid-seeking network, Food City Employee No. 5 said that the pill seekers were traveling in groups to and from pill mill doctors in Florida and elsewhere.

485. "Unfortunately, come to find out years afterwards, talking to the Board [of Pharmacy] members and talking to the Pharmacy Board personnel, they would come up with buses and [look for pharmacists willing to fill]," Food City Employee No. 5 said. "They had the same transportation and stuff — it was a big network. They would get on the phone, and call around, and stuff like that, and after about one or two of those days, you kind of knew that you weren't going to fill those prescriptions whatsoever."

486. During his time at Food City, there was never a corporate directive from Food City about the out-of-state prescribers. Individual pharmacists made their own calls on whether to fill.

487. "Initially, we would call the doctors in Florida and they verified the prescriptions," Food City Employee No. 5 said, explaining that it was particularly challenging as a floater, because if the patient was an established customer, they had an existing relationship with the patient and the standard response would be to fill.

488. "Normally, the patient was a patient of the pharmacy I was filling in for, and I wasn't a regular staff member there, so I kind of gave the benefit of the doubt for that," Food City Employee No. 5 said. "[The normal pharmacist] had already previously filled for that patient."

489. As a floater, it was tough to know what the current trends and concerns were at a particular location you were filling in at. It was also important to make sure the location had a record of any information gleaned during a floater shift. Food City Employee No. 5 said that when dispensing opioids or any unusual orders, he was diligent about leaving notes for the regular staff or the regular PIC. "To make sure they know, 'hey, I filled that prescription; if you have any questions please give me a call,'" he said.

490. "Most locations have folders with notes," Food City Employee No. 5 said. Sometimes he called the PIC or told the pharmacist on duty. Food City Employee No. 5, who

worked at most stores in east Tennessee during his tenure, never saw a bad doctor list or similar document.

491. "I did not ever see a bad doctor list," Food City Employee No. 5 said. "But I know that the doctor at the Bearden clinic was investigated several times by the Board examiner."

492. Food City presumably knew, too, but chose to still fill for the Bearden Healthcare Associates. Corporate did not seem to be working to identify pill mill doctors, either. Food City Employee No. 5 said that Food City corporate never had a "list of doctors sent out that we wouldn't fill for."

493. Unless the pharmacist was proactive and watching for Board actions, or the Board inspector came by and mentioned a doctor had been sanctioned, "there was not a lot of communication in pharmacy," he said.

494. In the August 2016 Tennessee Board of Pharmacy Disciplinary Action Report, Food City No. 674 was cited because it had "[f]ailed to adhere to rules and/or statute regarding prescriber and dispenser responsibilities; a pharmacist may compound and dispense prescription drugs and devices and related materials only in a pharmacy practice site which is duly licensed by the board and which operates in a pharmacy practice site which is duly licensed by the board and which operates in compliance with Tennessee and federal laws and rules governing the practice of pharmacy; distributed or dispensed controlled substances in violation of §53-11-308."[262] The Board of Pharmacy ordered that Food City No. 674 would have to submit to practice monitoring by Board investigators with terms and assessed costs not to exceed $10,000.[263]

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[262] August 2016 Tennessee Disciplinary Action Report, https://www.tn.gov/content/dam/tn/health/dar/August.2016.DAR.pdf.

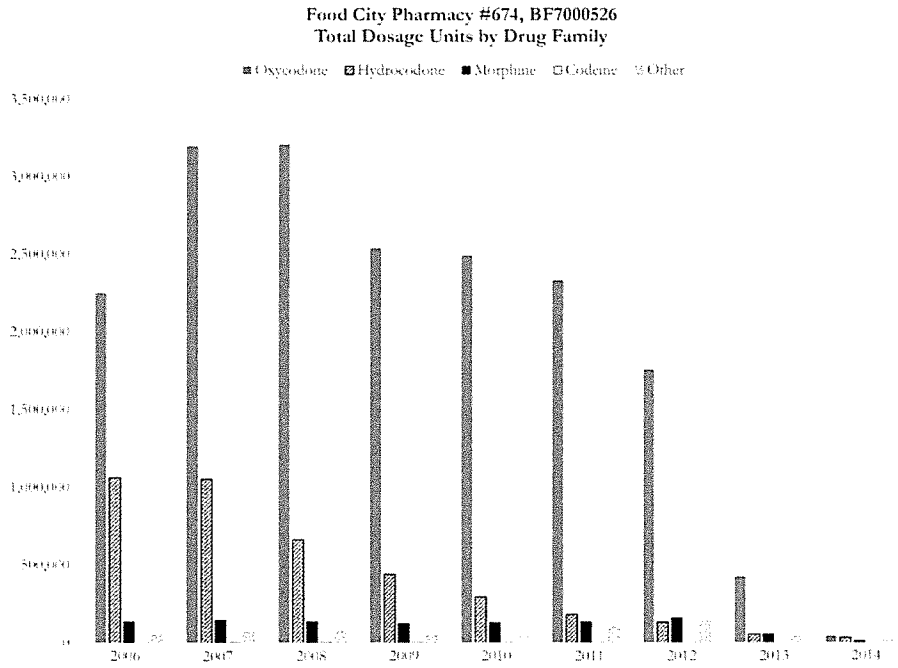
[263] *Id.*

b) Food City No. 694 – 284 Morrell Road, Knoxville, Tennessee

495. Knoxville's Food City No. 694 had nationally high oxycodone numbers as well, but not as high as its sister store, No. 674, located just two-and-a-half miles away. Food City No. 694 from 2006 to 2014 dispensed some 6,213,918 doses of opioids or an astounding 249,894,898 MME, enough at the highest bounds of the recommended MME per day (90 MME/day) for the store to supply an average of 1,086 opioid prescriptions per day every day for seven years.

496. According to the Washington Post, Food City No. 694 received enough opioids for 13 pills per year for each of the 44,776 men, women and children who live within five miles of this pharmacy.[264]

497. Below is a table taken from the DEA's ARCOS database depicting the glut of opioids dispensed at this Food City which saturated Knoxville:



[264] Armand Emamdjomek, *et al.*, *How many pain pills went to your pharmacy?*, The Washington Post (Feb. 25, 2020), https://www.washingtonpost.com/graphics/2019/investigations/pharmacies-pain-pill-map/.

498. Food City Employee No. 6 worked for Food City in Knoxville from June 2011 to November 2013. She started as pharmacy technician, studied on her own to become a certified technician, and passed a state board test to become certified sometime in 2013.

499. Food City Employee No. 6 worked at the Food City store at the Deane Hill shopping center on 284 Morrell Road in Knoxville, Store No. 694. She also floated five or six times to the Bearden Center store, No. 674, on Kingston Pike in Knoxville.

500. She did data entry tasks, entering information on patients, physicians and prescriptions for each prescription, and checking out patients at the register. She saw many patients at both stores with prescriptions for opioids. At the Deane Hill store, there would be a line out the door, and the patients would arrive on the same days with the same prescriptions from the Bearden Healthcare Associates.

501. "It was the same prescription over and over and over," she said. "We would get bombarded one or two days a week. It was a lot of workflow at the same time."

502. At the Bearden Store No. 694, the patients would seem to come in one at a time, leave, and then the next one would come in. The patient traffic was more intense at the Bearden store. The patients at that store seemed to be more laid back, but their prescriptions were much higher in volume. It was a steady flow of opioid patients all day.

503. "I remember leaving there really tired. Just worn out with it," she said. "The opioid situation was getting overwhelming at that time."

504. The patients would come to the Deane Hill Store No. 694 and drop the exact same sheet off with the exact same prescription from the Bearden Healthcare Associates. The pharmacists called the prescription a "cocktail."

505. Food City Employee No. 6 recalls it was for three narcotics – hydrocodone, which they said was for acute pain; Oxycontin, which they said was for long-term, daylong pain relief; and Neurontin, which they said was for nerve pain. The prescriptions were for brand name versions of these drugs.

506. Even to her untrained eye, it was evident that the patients were being overprescribed narcotics. "They didn't look like they needed that amount of pain medication," she said. "There were a lot of patients that I thought did not need what they were getting and were not using it correctly." But she did not recall any of the pharmacists cautioning her or anyone on the staff about warning signs for suspicious patients.

507. Several pharmacists told Food City Employee No. 6 that the store had an agreement with Bearden Healthcare Associates to fill whatever they sent them. "They said 'just fill whatever comes from this office,'" she said. As a young employee with no training of her own, she did not ask questions about it.

508. The store manager at Deane Hill, "Miss Moore," was very involved in the pharmacy operations. Miss Moore pushed pharmacists to fill prescriptions for opioids because she wanted her numbers to look good. Moore considered her store to be in competition with the Food City Store No. 674 for sales, including pharmacy sales, and made comments about competing with the Bearden store.

509. Occasionally, pharmacists would refuse to fill prescriptions. Food City Employee No. 6 recalled cases of patients being refused their prescriptions and the patient walking away upset, prompting store manager Moore to come back to the pharmacy and ask why the prescription was not filled.

510. Moore would ask why the patient left upset, and "[w]hy did they leave my store mad?" Food City Employee No. 6 recalls Moore telling a pharmacist: "You need to fix it." She recalled instances when the patient returned after being refused, or went to the drive-through, and the prescription would be filled.

511. "It would make us feel very awkward," Employee No. 6 said. "It was a weird situation."

512. In order to get around the limits on opioid prescriptions set by TennCare, Tennessee's Medicaid agency, the Bearden Healthcare Associates would write two prescriptions for each narcotic. Then, the Food City pharmacy would "split bill" for the prescription, charging TennCare for one and getting paid in cash for the other.

513. Food City No. 694 did so to avoid scrutiny from TennCare and to be able to prescribe 120 doses of oxycodone when TennCare would only pay for 56 for a 28-day supply. It was an accepted store policy to engage in such split billing.

514. Food City Employee No. 6 recalled one patient paying $2,000 in cash for a portion of a prescription for a controlled substance. It was for a brand name drug, possibly Oxycontin or Percocet, she said.

515. "It was the most money I had ever seen," Employee No. 6 explained. "It was just laid out on the counter." She had to request a co-worker help her count it. "That was a big red flag," she said. "I thought, 'How can this person afford this if they are on TennCare?'"

516. Food City Employee No. 6 recalled that some pharmacists on occasion would question this practice with Miss Moore, but their questions were never answered.

517. At the Deane Hill store, most of the pharmacists were "floaters" and they would change constantly. "Every day I worked with someone different," Employee No. 6 said. "I can't even tell you their names."

518. That was a problem, as she had to learn someone's work style, personality, and procedure nearly every day.

519. She recalled that the volume of opioid traffic, the warning signs about patients that were present, and the pressure from management led on more than one occasion to conversations with pharmacists about their nature of their jobs.

520. The pharmacists seemed resigned to following instructions and not exercising the rights and responsibilities they had under the law. "They just said they did what they were told to do," Employee No. 6 said. "They got their direction from the doctors and from the management. They were just doing their job and making sure the prescriptions were accurate. That's how they viewed their jobs."

521. Food City Employee No. 6 does not recall any pharmacist warning or cautioning the staff about filling prescriptions from certain physicians, including the physicians from the Bearden Healthcare Associates.

522. Food City Employee No. 6 did not receive any pharmacy-specific training from Food City before starting work in the pharmacy.

523. She did not receive any training about "red flags" or warning signs of suspicious prescribers or patients. The Food City stores kept no list or maintained no database of prescribers who were under investigation or were otherwise considered suspect.

524. The Tennessee Board of Pharmacy put Food City No. 694 on two years of probation in May 2015.[265] In addition, the Pharmacist-in-Charge and all the dispensing pharmacists were required to complete 15 hours of continuing pharmaceutical education in dispensing of controlled substances.[266]

c) Food City No. 616 – 11501 Hardin Valley Rd, Knoxville, Tennessee

525. Food City No. 616, located at 11501 Hardin Valley Road in Knoxville, approximately a 15-minute drive from Food City No. 674 and No. 694, also ordered disproportionately high numbers of oxycodone. Food City No. 616 from 2006 to 2014 dispensed some 3,000,870 doses of opioids or an astounding 111,238,720 MME, enough at the highest bounds of the recommended MME per day (90 MME/day) for the store to supply an average of 483 opioid prescriptions per day every day for seven years.

526. According to the Washington Post, Food City No. 616 received enough opioids for 46 pills per year for each of the 9,302 men, women and children who live within five miles of this pharmacy.[267]

527. Below is a table taken from the DEA's ARCOS database depicting the glut of opioids dispensed at this Food City which saturated Knoxville:

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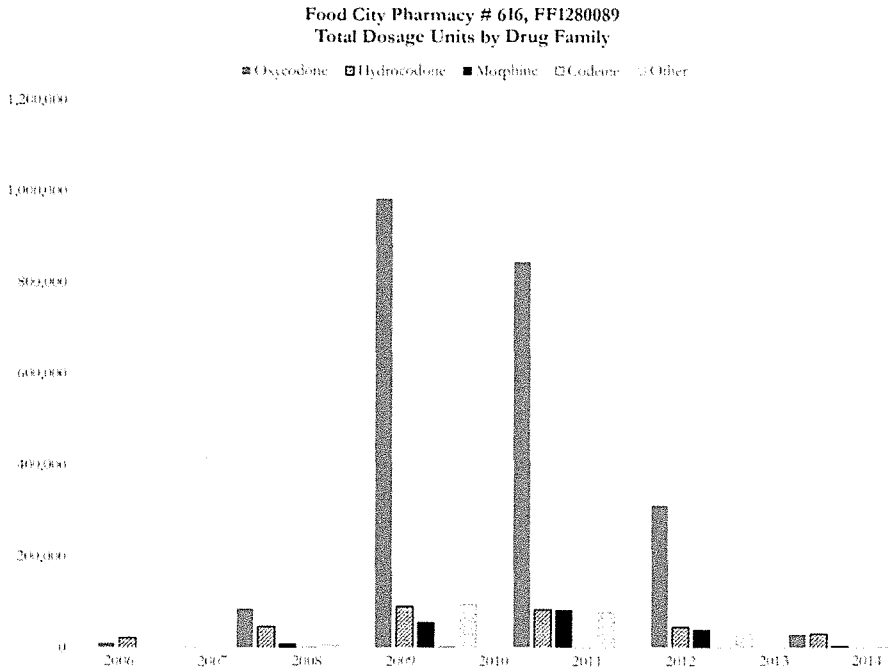
[265] Minutes, Tennessee Board of Pharmacy (May 11-12, 2015), at 23, https://www.mytn.gov/content/dam/tn/health/documents/Pharm051115.pdf.

[266] *Id.*

[267] Armand Emamdjomek, *et al.*, *How many pain pills went to your pharmacy?*, Washington Post (Feb. 25, 2020), https://www.washingtonpost.com/graphics/2019/investigations/pharmacies-pain-pill-map/.



528. According to a former assistant store manager at Food City No. 616, Food City Employee No. 8, who worked at No. 616 from 2011 to 2015, the Hardin Valley location was among the three to five top-performing Food City pharmacies at some points during his tenure at the store. Even as a non-pharmacist, Food City Employee No. 8 witnessed conduct that made it patently obvious that the pharmacy was illegally dispensing opioid prescriptions at Food City No. 616.

529. The Hardin Valley pharmacy (No. 616) and the Food City Pharmacy at Store No. 674 would some weeks bring in 300,000 opioid pills, Food City Employee No. 8 said, based on his conversations with Pharmacy Manager Ellen Phillips.

530. Especially during certain periods of the month, such as the beginning of the month, the pharmacy would have a long line of customers that extended beyond the six waiting seats situated near the pharmacy, which were all filled. The pharmacy was especially busy during the

peak times of 10:30 a.m. to noon and 3:30 p.m. to 5 p.m. "You knew the times of the month of when people were getting their prescriptions," he said.

531. Phillips would sometimes ask Food City Employee No. 8 to stand behind the pharmacy counter during busy times to act essentially as security "because of the shadiness of the people they were filling for," he said.

532. In one particularly egregious incident, Food City Employee No. 8 recalled when he was called to stand behind the pharmacy counter and observed an "old lady" who paid in cash for three or four different narcotic prescriptions, each with triple-digit pills, including 250 pills of hydrocodone or Percocet and 180 pills of Valium or another opiate.

533. "That was how many years ago? – I still remember that prescription they were trying to fill," he said, confirming that the pharmacy did fill the prescriptions. "[The pharmacy staff] knew that what they were doing was not right. However, they're getting breathed down by their neck by their upper management or supervisors saying, 'You have to do this' or 'Why isn't this being filled?' or 'Why are your numbers going down? – you have to go after more clinics.'"

534. Based on his conversations with Phillips and pharmacy technicians, Food City Employee No. 8 said pharmacy staff "had reason to believe that [opioid] prescriptions were bogus," adding that the pharmacy filled a lot of prescriptions from two pain clinics: Bearden Healthcare Associates and East Knoxville Healthcare Services (EKHCS), 509 Lovell Road in Knoxville run by Sylvia Hofstetter who was recently sentenced.

535. On February 13, 2020, a jury returned guilty verdicts against Hofstetter for a Racketeer Influenced and Corrupt Organization (RICO) conspiracy, a drug conspiracy, money laundering and maintaining drug-involved premises, and guilty verdicts against three others for maintaining drug-involved premises. The drug conspiracy involved the distribution of over 11

million tablets of oxycodone, oxymorphone and morphine that generated over $21 million of clinic revenue, with a corresponding street value of $360 million. The conspiracy involved four separate clinics in Tennessee, which, the evidence showed, were essentially pill mills.[268]

536. According to the Government's Fourth Superseding Indictment, Hofstetter and her co-conspirators had operated pain clinics in Knoxville and Lenoir City, Tennessee from about 2011 until 2015, including the EKHCS clinic in Knoxville, which was an 11-minute drive from Food City Store No. 616. From in or about September 2013 through in or about March 2015, medical providers at EKHCS prescribed opioids and other controlled substances to thousands of purported pain patients in exchange for grossly excessive fees. The vast majority of the prescriptions were unreasonable and medically unnecessary. Many of these prescriptions were filled at Food City Store No. 616.

537. Hofstetter was the owner of several pain clinics, but was not a physician and did not write prescriptions herself. However, the following individuals were indicted with her and wrote prescriptions at her clinic. The Medicare spending below reflects prescriptions written by her indicted co-conspirators: Physician Assistant Alan Pecorella (2014 spending); Nurse Practioner Cynthia Clemons (2014 and 2015 spending); Nurse Practioner Holli Womack, a.k.a. Holli Carmichael (2014 spending). During the time period 2014 through 2015, Medicare Part D plans paid some $1,009,890 in claims for CII and CIII drugs they had prescribed[269]:

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[268] Press Release, Department of Justice, *Federal Jury Convicts Four Defendants for Operating Knoxville-Area Pill Mills* (Feb. 14, 2020), https://www.justice.gov/opa/pr/federal-jury-convicts-four-defendants-operating-knoxville-area-pill-mills.

[269] This table compiles Medicare provider utilization and payment data available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Part-D-Prescriber.

DRUG	TOTAL MEDICARE CLAIMS	TOTAL MEDICARE COSTS ($)
FENTANYL	47	$5,199.51
GABAPENTIN	1,223	$24,118.44
HYDROCODONE-ACETAMINOPHEN	290	$7,275.99
MORPHINE SULFATE	16	$161.58
MORPHINE SULFATE ER	901	$87,989.40
OPANA ER	493	$230,771.38
OXYCODONE HCL	3,039	$175,577.49
OXYCODONE-ACETMINOPHEN	338	$25,390.04
OXYCONTIN	340	$180,234.41
OXYMORPHONE HCL	83	$21,636.01
OXYMORPHONE HCL ER	990	$251,536.18
GRAND TOTAL	**7,760**	**$1,009,890.43**

538. Transactions at the Hardin Valley Food City pharmacy were often "all cash," and Food City Employee No. 8 was sometimes called back to the pharmacy to do "pickups," or to take money out of the cash register because there was "way too much money in there," he said. In fact, Ellen Phillips told him that she had been robbed at gunpoint in the pharmacy some years prior (approximately 2009).

539. Food City Employee No. 8 said that at about 8:30 a.m. every morning – or at least every other morning – a delivery man in an unmarked white economy van would show up at the store and park in the fire lane before carrying in totes stacked as tall as he was that were filled with narcotic medications.

540. Food City Employee No. 8 said he observed "obvious drug deals and drug exchanges" that took place in the store's parking lot. The interactions could be seen on security camera footage, he said. "They were pretty clear as day," he said about being able to recognize that the interactions were drug deals.

541. Manager of Pharmacy Operations Ken Slagle and Executive Vice President Mickey Blazer from Food City's headquarters office pressured Phillips, Pharmacy Technician Jessica Eads, a pharmacy technician named Haley and other pharmacy staff to fill and increase opioid prescriptions, Food City Employee No. 8 said.

542. "[Phillips] knew what she was dispensing was unlawful, but she was required by Food City EVP Mickey Blazer – who at the time was over the pharmacy, then he became a VP and now he's back over the pharmacy and gas – they strongly enforced, 'You have to fill these prescriptions. This is where we're making our money, and we want to make money.'" Slagle told the pharmacy staff that it was the expectation that if the prescription was dated and signed there is no reason to deny it.

543. Phillips told Food City Employee No. 8 about conversations she had with Slagle, who had come from Kroger and "doesn't know a lick about pharmacy," Food City Employee No. 8 said.

544. Around the time regulators cracked down on Food City, Slagle visited the store every day or every other day for a period of months and was a "thorn in the ass" to Phillips and the pharmacy staff, Food City Employee No. 8 said. Slagle would stay at the store for 30 minutes on a short visit and longer at other times.

545. Food City Employee No. 8 observed Manager of Pharmacy Operations Slagle in the store, but was not part of the conversations Slagle had with pharmacy staff. "All I knew was

the pressure that the pharmacists and the techs were getting to make sure that things were done the way they needed to be done," he said. "I could feel that they felt pressure of their job – if they didn't just shut up and do what they had to do. It was very clear."

546. Phillips, Eads – who was essentially second in charge at the pharmacy – and other pharmacy staff talked to Food City Employee No. 8 about the pressure they felt from Slagle. "They hated it," he said. "It got to the point where the techs would actually talk back to Ken. It created a very sour working environment . . . ." Food City Employee No. 8 said Manager of Pharmacy Operations Slagle's behavior toward pharmacy staff was "borderline harassment," and that he liked to be "very hands-on."

547. Food City Employee No. 8 described Food City management, particularly Slagle, as "money hungry." The pharmacy business had become Food City's "cash cow" and "they were going to milk it dry."

548. Pharmacy staff make sure that the prescription volumes were high, Food City Employee No. 8 said. "They had to have a certain number of scripts going out. They had to be able to maintain profits to where it was economical for them to have that extra worker," he said, referring to an additional staff member who would assist at the pharmacy. "When you're pushing out that much, one other person is really not helping out that much."

549. "The pharmacists always had filled to whatever the needs were," he said. "That was the Food City way – get it, get it, get it."

550. Phillips, who left the Hardin Valley store shortly before Food City Employee No. 8 transferred to the Lenoir City store in 2015, was investigated for wrongful death in connection with a man who died from an opioid overdose. The man had received opioid prescriptions at the Hardin Valley store while Phillips was pharmacy manager there, Food City Employee No. 8 said.

551. The case was eventually dismissed because Phillips was not at the pharmacy when the man picked up the opioids on which he overdosed, Food City Employee No. 8 said, adding that Phillips had been on leave while she was pregnant with her daughter.

552. "What they tried to say was he had been getting that prescription for some time and that she never addressed the severity of the addiction to it," he said.

553. According to minutes from a May 2015 meeting of the Tennessee Board of Pharmacy, Food City Pharmacy Store No. 616 was placed on a two-year probation. The pharmacist in charge and all dispensing pharmacists from the store were ordered to complete 15 in-person hours of continuing pharmaceutical education in dispensing of controlled substances, quarterly monitoring report of controlled substance dispensing, drug review and case cost.[270]

554. After the Food City pharmacy at Store No. 616 lost its license to dispense opioids for several months, the pharmacy went from bringing in $12,000-$15,000 per week to $2,400 per week, Food City Employee No. 8 said. Prior to having the license revoked, the pharmacy brought in as much as $30,000 per week.

555. Knowing how little the store was bringing in on the grocery side, Food City Employee No. 8 said the pharmacy's high sales numbers were the "only way that store was staying in business."

556. Once regulators intervened, the pharmacy's sales numbers dropped, Food City Employee No. 8 said: "The toll that it took financially on the company was astounding. It was crazy. Their money train came to an end."

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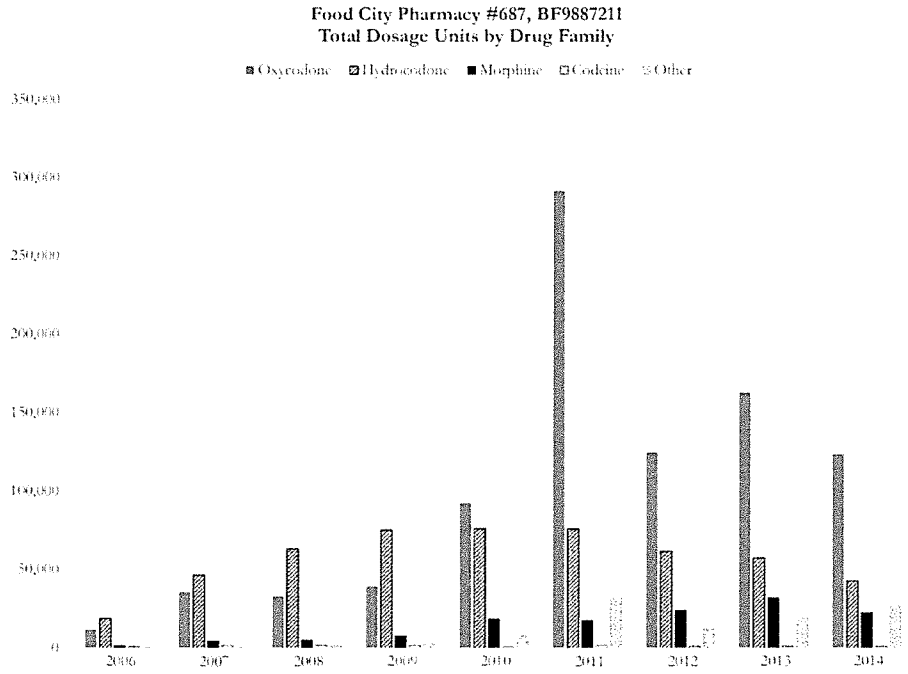
[270] Minutes, Tennessee Board of Pharmacy (May 11-12, 2015), at 22-23, https://www.mytn.gov/content/dam/tn/health/documents/Pharm051115.pdf.

d) Food City No. 687 – 2712 Loves Creek Rd., Knoxville, Tennessee

557. While the Loves Creek Food City pharmacy dispensed relatively fewer opioids than other Knoxville pharmacies, its numbers were still considerable. Food City pharmacy Food City No. 687 from 2006 to 2014 dispensed some 1,676,450 doses of opioids or 45,120,463 MME, enough at the highest bounds of the recommended MME per day (90 MME/day) for the store to supply an average of 196 opioid prescriptions per day every day for seven years.

558. According to the Washington Post, Food City No. 687 received enough opioids for seven pills per year for each of the 20,032 men, women and children who live within five miles of this pharmacy.[271]

559. Below is a table taken from the DEA's ARCOS database depicting the glut of opioids dispensed at this Food City which saturated Knoxville, much of it oxycodone:



[271] Armand Emamdjomek, *et al.*, *How many pain pills went to your pharmacy?*, Washington Post (Feb. 25, 2020), https://www.washingtonpost.com/graphics/2019/investigations/pharmacies-pain-pill-map/.

560. According to Food City Employee No. 9, who worked as the manager of the Food City No. 687 at 2712 Loves Creek Road in Knoxville, when she began working at the pharmacy in October 2011, the pharmacy regularly was filling prescriptions for "opioids and the cocktail that usually went along with it" – oxycodone, alprazolam and the muscle relaxant Soma, she said, adding that she learned about this from pharmacy technicians who had been at the store and continued working there after Food City Employee No. 9 took over.

561. "The location would previously fill for prescribers that were not within a legitimate geographic radius of the location," she said, adding that many of the prescriptions came from out-of-state pain clinics in Georgia and Florida, and from clinics in the Nashville area.

562. The pharmacy technicians told Food City Employee No. 9 that it "appeared that there was a van that would bring all these people from the doctor's office to the pharmacy to have those prescriptions filled," and that the vans were connected to prescriptions coming for suspicious Georgia pain clinics. Multiple pharmacy technicians "told me that they had always filled [the out-of-state opioid/cocktail prescriptions] before and that they were uncomfortable with filling them."

563. Food City Employee No. 9 said that when she took over at Food City Store No. 687, she started refusing to fill prescriptions for at least "dozens" of customers who came in with opioid/cocktail prescriptions from out-of-state. "Until I started refusing the prescriptions, those people would come in and ask me to fill them," she said.

564. When customers came in with an opioid prescription, Food City Employee No. 9 said she would verify that it was a legal prescription, that it was not too soon to be filled and that the customer had not gotten the same prescription filled at another pharmacy.

565. Unlike at other pharmacy chains where she had worked, Food City Employee No. 9 said Food City did not have a system in place to document instances when pharmacists refused to fill a prescription and the reasons for not filling it.

566. "The only way to do it would be to put … notations on the [customer] profile or to call another pharmacy and alert it [about the customer]," she said. "Food City did not have a system in place like I had at Walmart where you could document a refusal to fill a prescription and the reasons why."

567. At Food City, pharmacists could use the notes section of a customer's profile in the company's computer system to document that they had refused to fill a prescription and the reasons for doing so, such as when a customer tried filling a prescription too early. In such a case, Food City Employee No. 9 might write something like, "Caution _ days supply."

568. Pharmacy staff were not required to make notes in a customer's profile when they refused to fill a prescription. According to Food City Employee No. 9, even if they did make a note, doing so would not necessarily help pharmacists at other locations if the same customer came in because Food City did not require pharmacy staff to check the notes section of a customer's profile.

569. Checking the notes section was "not required, not necessary to fill a prescription," she said. Additionally, Food City's computer system "wouldn't automatically flag [pharmacists] to look" at the notes section of a customer's profile to see if another pharmacist had made any notes. "Food City had no way to report why you were refusing to fill a prescription," she said.

570. When entering notes about patients whose prescriptions she refused to fill, Food City Employee No. 9 said she had to be careful to "do it in such a way to not get myself in trouble

… You don't want to put a note on there that says something derogatory, like 'drug abuser.' You keep those kinds of characteristics to yourself."

571. She did fill some prescriptions for Bearden Healthcare Associates patients, but those patients "were also on other regular medications – it wasn't just opioids," she said.

572. Food City Employee No. 9 believes she kept a list of suspicious prescribers, "but it wasn't anything official." It might have been a piece of paper that she added names to over time, she said, adding that Food City did not have a policy requiring pharmacies to keep a suspicious prescriber list.

573. Manager of Pharmacy Operations Ken Slagle – who oversaw pharmacies in the Knoxville area – visited Food City Employee No. 9 at her pharmacy and pressured her to fill more opioid prescriptions, she said.

574. "I was under the impression from [Manager of Pharmacy Operations Slagle] that my job was in jeopardy if I didn't knuckle down and fill more opioids," Food City Employee No. 9 said. "I needed to increase the prescription numbers and profits, and the medication with the highest profit margin is the opioids."

575. Food City Employee No. 9 said she had to send weekly reports with the number of prescriptions sold, sales data and inventory to Food City's district office. The reports did not specifically show how many opioids were being dispensed, "but … if you knew what you were looking at, you could look at those days and get an idea because your sales would be higher those days," she said. Both Manager of Pharmacy Operations Slagle and her direct supervisor, Pharmacy Services Supervisor Tom Geoghagan, would have received copies of the reports, she said.

576. Food City Employee No. 9 communicated with Manager of Pharmacy Operations Slagle by email, phone and in-person, and that it was during in-person conversations when Slagle

pressured her to fill more opioid prescriptions. She said that when she emailed with Slagle, she always copied Executive Vice President Blazer and her store manager "to cover myself."

577. She explained that Tennessee's Board of Pharmacy set limits on how many opioids pharmacies could dispense relative to their volume of other prescriptions.

578. "I know there were times that ceiling had to be raised for [her store] to get the number of [opioid] prescriptions filled that they wanted to get filled," she said. "Opioids had a very high profit margin."

579. Asked if she thought Food City did enough to regulate the dispensing of opioids, Food City Employee No. 9 said: "No. My personal feeling was they would have liked me to fill more than I did."

580. According to Relator, during his time as a Pharmacy Technician at Store No. 687 in Knoxville, he witnessed Manager of Pharmacy Operations Slagle come into the store and tell Food City Employee No. 9 – the pharmacy manager – that he wanted to see the store's average prescription price increase.

581. Relator also recalls seeing a document from one of Food City Employee No. 9's performance reviews, which was conducted by Slagle, stating the average prescription price is too low.

582. In Relator's experience, Manager of Pharmacy Operations Slagle and other Food City management constantly bragged about how great the company's top-performing pharmacies were, singling out the Gatlinburg (Store No. 611) and Hardin Valley (Store No. 616) locations, both of which were later raided.

5. *Maryville, Tennessee (Food City Nos. 647 and 651)*

583. Maryville, Tennessee has been a hotbed of activity for opioid pill mills. For example, eleven health care professionals associated with the Breakthrough Pain Therapy Center, 2211 East Broadway, Maryville, Tennessee, have been indicted and/or sentenced for drug trafficking. There were numerous warning signs that the clinic was no clinic at all:

- Cash only payments
- Gun-toting workers
- Entire families as patients with identical pain complaints
- No medical referrals
- No prior testing
- No medical equipment
- No appointments
- A boss with zero medical experience[272]

584. Even after the clinic was raided in 2010 and the owners arrested as drug dealers, the rest of Breakthrough staff went to work at other pill mills in town or set up their own pain clinics. So, beginning in 2014 prosecutors indicted nine former Breakthrough staff members as well.[273]

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[272] Jamie Satterfield, *Feds prosecute pain-clinic workers as drug dealers*, Knoxville News Sentinel (Nov. 27, 2016), https://www.usatoday.com/story/news/nation-now/2016/11/22/pill-mill-drug-dealer-prosecutions/94246152/.

[273] Press Release, U.S. Attorney, E.D. Tenn., *Nine Medical Practitioners Indicted In Conspiracy To Distribute Controlled Pain Medication As Employees Of Breakthrough Pain Therapy Center In Maryville* (Oct. 16, 2014), https://www.justice.gov/usao-edtn/pr/nine-medical-practitioners-indicted-conspiracy-distribute-controlled-pain-medication.

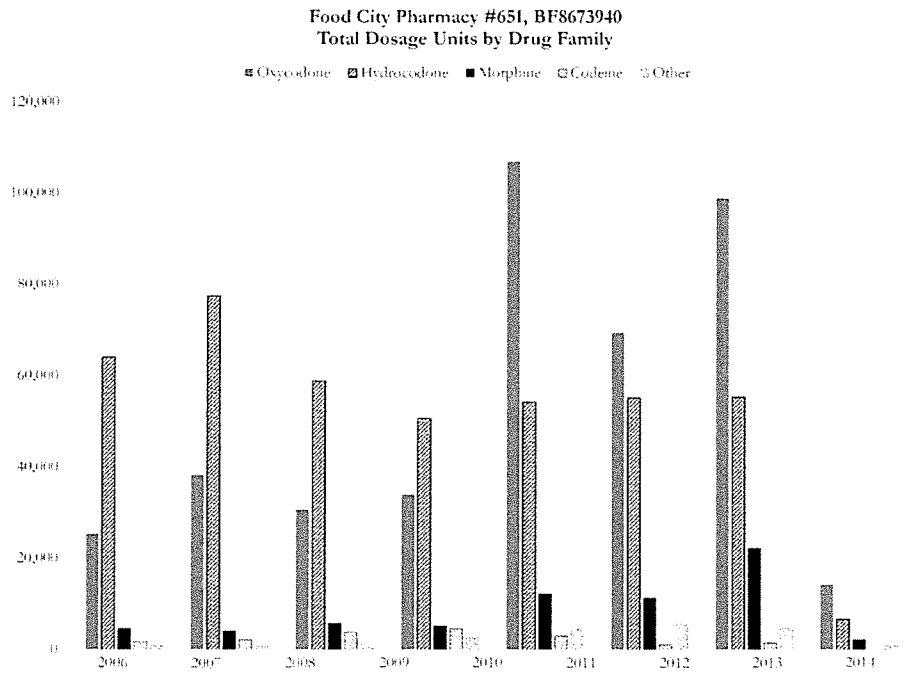
585. Food City Employee No. 10 worked for Food City Pharmacy from 2011 to 2015 as a Pharmacy Technician and Certified Pharmacy Technician at Store No. 651 located at 1610 West Broadway, Maryville, Tennessee and Store No. 647 located at 2135 East Broadway, Maryville, Tennessee. Store No. 647 was located one block away from the Breakthrough Pain Therapy Center.

586. Food City No. 651 from 2006 to 2014 dispensed some 945,075 doses of opioids or 21,228,055 MME, enough at the highest bounds of the recommended MME per day (90 MME/day) for the store to supply an average of 95 opioid prescriptions per day every day for seven years.

587. According to the Washington Post, Food City No. 651 received enough opioids for 4 pills per year for each of the 24,145 men, women and children who live within five miles of this pharmacy.[274]

588. Below is a table taken from the DEA's ARCOS database depicting the glut of opioids dispensed at this Food City which saturated Maryville, particularly Oxcodone:

[274] Armand Emamdjomek, *et al.*, *How many pain pills went to your pharmacy?*, Washington Post (Feb. 25, 2020), https://www.washingtonpost.com/graphics/2019/investigations/pharmacies-pain-pill-map/.

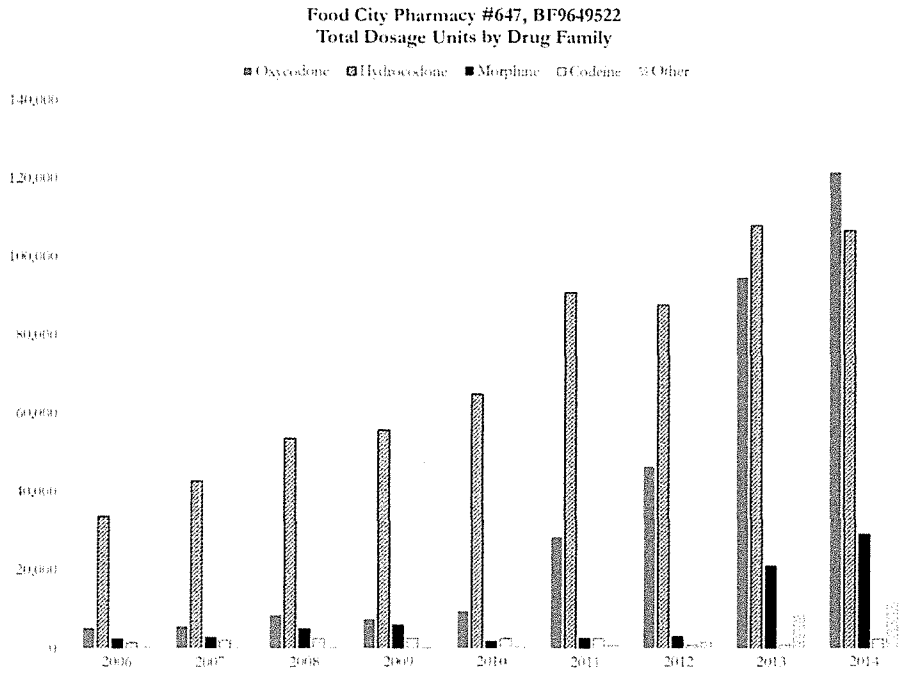


589. Food City No. 647 from 2006 to 2014 dispensed some 1,089,935 doses of opioids or 15,634,358 MME, enough at the highest bounds of the recommended MME per day (90 MME/day) for the store to supply an average of 68 opioid prescriptions per day every day for seven years.

590. According to the Washington Post, Food City No. 647 received enough opioids for 4 pills per year for each of the 25,573 men, women and children who live within five miles of this pharmacy.[275]

591. Below is a table taken from the DEA's ARCOS database depicting the glut of opioids dispensed at this Food City which saturated Maryville, including both oxycodone and hydrocodone:

[275] *Id.*



592. Food City Employee No. 10 joined Food City in 2010 as a front-end manager, managing the cashiers, baggers, and grocery clerks at Store No. 651 in Maryville, Tennessee. After about six to eight months, she stepped into a role as a Pharmacy Technician at the same store until the pharmacy closed in late 2012. At the beginning of 2013, Food City Employee No. 10 started as a Certified Pharmacy Technician at Food City Store No. 647 on the other side of town in Maryville.

593. The pharmacy manager in the stores where Food City Employee No. 10 worked in turn reported to Pharmacy Services Supervisor Tom Geoghagan, who visited the store on occasion. District Manager Randy Williams came with Geoghagan on store visits about 30% of the time, she said.

594. Food City Employee No. 10 said the pharmacy at Store No. 647 in Maryville dispensed a high volume of the "typical cocktail" of medications – morphine, oxycodone, and Xanax – from prescriptions written by doctors at a handful of pain clinics in the area. "That's pretty

much all they prescribed, and we did a lot of volume in that," she said, adding that the customers "100% didn't need the medications."

595. "At that time there were probably four or five of those clinics that were really prevalent, and once one would get closed down another one would just open up," she said.

596. Food City Employee No. 10 also said she learned after the fact that Food City had filled prescriptions from a doctor who was writing prescriptions out of a hotel room, though she could not remember the doctor's name. The doctor's clinic was then shut down at some point.

597. Many of the Food City pharmacy customers did not have insurance and paid for the medications entirely in cash "so there was no paper trail," Food City Employee No. 10 said.

598. In late 2014 or early 2015, Food City implemented a policy stating it would not accept cash payments for opioids if the prescription came from a pain clinic, with exceptions for some oncology patients. Food City instead encouraged customers to pay using a "throwaway" prepaid debit card, which customers could purchase at the same store. "Customers could walk 10 feet away, pull [the prepaid cards] off the side of the register and come back to the pharmacy," Food City Employee No. 10 said. "That's what they would do."

599. Food City Employee No. 10 said she began seeing older patients come in with the same set of prescriptions "that was just really too much for them," but Store No. 647 dispensed the medications anyway.

600. Common prescriptions were ones with "sig codes" Oxy 20 IR, Oxy QID (taken four times a day), Xanax 2 (prescribed for up to three or four times a day) and morphine (prescribed for up to three times a day), she said.

601. "It didn't make sense," Food City Employee No. 10 said, explaining that the dosage levels and frequency of taking the medication did not seem appropriate for the customers.

602. Over time, Food City Employee No. 10 said she noticed that regular customers who were initially "vibrant" and enjoyed conversing with her were starting to be affected by the cocktail of medications.

603. "It made me so sad to see people close to my age and also the really elderly people that had no idea. They were just in pain, and it was rather than finding out the root cause, let me just give them all of this," she said. "I watched patients decline. You could visibly see after an amount of time people being almost run down. They were initially vibrant and would have conversations with you.... You would see them [at later dates] and they would be just zonked out and you would just see it was almost like it was leading them to worse health."

604. Pharmacy staff also worried about patients going through withdrawal symptoms if they refused to fill their prescriptions. "You would worry about the patient going into withdrawal," she said. "How is an 89-year-old going to react to being pulled off of all this?"

605. Because of pressure from Food City management, pharmacy staff had to continue dispensing medications to those customers, Food City Employee No. 10 said.

606. Food City Employee No. 10 said she recalled visits by Pharmacy Services Supervisor Tom Geoghagan, who would sometimes go into a back room with the pharmacy manager for private discussions when Food City was trying to get the DEA to raise the limit for the volume of controlled substances the pharmacy was allowed to dispense in a month. The company successfully got the agency to raise the pharmacy's limit between five and ten times during Food City Employee No. 10's few years at the pharmacy, she said.

607. Food City Employee No. 10 said the pharmacy at Store No. 647 was filling about 250-300 prescriptions per day, at least 30% of which were controlled substances. She estimated that the pharmacy doubled the volume of opioid pills it dispensed during her few years there.

608. "And there was a time where another pharmacy down the street – Village Pharmacy – had closed, and they had us absorb all of the patients," she said. "It was something that was advertised, that customers could go to Food City to fill their prescriptions. And with that also came an influx of these pain contract patients."

609. Pharmacy Services Supervisor Geoghagan and other Food City executives regularly pressured Food City Employee No. 10 and other pharmacy staff to fill opioids and to not turn away customers with opioid prescriptions, including via emails sent to pharmacy staff, Food City Employee No. 10 said. In addition to Geoghagan, Food City Employee No. 10 said she also recalled seeing emails from Executive Vice President Mickey Blazer, who worked out of Food City's corporate office.

610. "The amount of opioids that we dispensed was in no way a direct reflection of the staff at that store," she said. "We all really didn't feel great about it and didn't really feel comfortable with it. But the upper management – . . . district manager named Tom [Geoghagan] – he would visit the pharmacy and we would express directly, 'We're selling a lot of this; we're starting to meet DEA caps.' And he was like, 'Oh, we'll just get those raised.' It was pretty much if a prescription comes in for [opioids], don't turn people down."

611. "It was a push from corporate, a push from the district office to not put any caps on it," she said. "And it was explicitly said: 'We're not going to turn down money.' That was just kind of the general gist in the emails."

612. Pharmacy staff were still instructed to fill prescriptions even when they expressed to Food City's corporate staff that, "'We've hit this limit. We really don't want to take any more patients,'" Food City Employee No. 10 said. "It was, 'No, take every patient you can.'"

613. Pharmacy staff were instructed to fill prescriptions even for patients with pain contracts, patients who were new and had never been to a Food City and patients who had a history of opioid use according to the Controlled Substances Monitoring Database, Food City Employee No. 10 said.

614. "Our general consensus was, Food City wanted to fill that for profit," she said. "They didn't really care about the patient. It was not a company that cared about patients' wellbeing."

615. Food City Employee No. 10 said pharmacy staff feared situations where they had to deny customers' prescriptions because they ran out of certain medications.

616. "It would be very dramatic if you were in the pharmacy – it would be, 'We've got these patients coming in at the end of the week; are we going to have this [in stock] to fill it for them?'" she said.

617. Some customers threatened to call Food City's corporate office if they were denied prescriptions, a scenario pharmacy staff tried to avoid because of the response they would later receive from corporate. Food City Employee No. 10 said she recalls seeing emails from members of Food City's corporate team that stated, "'We got this customer complaint. What happened? Why did you not fill this?'"

618. Food City Employee No. 10 said she expressed her concerns to other pharmacy staff about filling such a high volume of opioid and cocktail prescriptions for patients who did not appear to need them.

619. "I discussed it with them several times, that I didn't feel comfortable with it, that we were hurting people," she said. "And they were like, 'Well, this is just part of it. They're going to get these prescriptions.' It was keep your job or don't. It was not their decision."

620. Food City Employee No. 10 recalled conversations she had with the pharmacy manager and other pharmacy staff during which she would relay information from corporate.

621. "She was basically giving us that information [from corporate] – 'I know we're taking all of this in and we don't really want to, but this is kind of what we have to do to secure our jobs,'" she said.

622. Food City Employee No. 10 said she refused to fill prescriptions for the "cocktail" of drugs (morphine, oxycodone and Xanax) a number of times. She remembers that whenever she saw a person who looked like a "body builder" come in – "tan, just left the gym, bringing in three scripts" – she would tell the pharmacy manager that she did not want to fill them.

623. Food City Employee No. 10's manager understood and let her "stock shelves while either filling the prescriptions herself or having another pharmacy technician do it," she said.

624. Food City Employee No. 10 said she decided to leave Food City because she felt she was playing a role in putting customers at risk.

625. "I started to feel I was playing a part in people overdosing and people not living the best life that they could," she said, adding that she never learned of any customers who overdosed. "That was my primary reasoning [for leaving]."

626. Other than checking a customer's driver's license upon checkout, Food City Employee No. 10 said "there wasn't a whole lot of verification" for prescriptions at Food City. Although pharmacy staff checked drivers' licenses, Food City did not have a system for scanning the licenses. Food City also did not have a policy requiring pharmacy staff to check the Controlled Substances Monitoring Database, though pharmacy staff typically did check the database for their own protection.

627. Food City Employee No. 10 said "not once" did she observe pharmacy staff call a doctor to ask questions about prescriptions that might have raised red flags. "There wasn't a whole lot of questioning," she said.

628. Food City had a policy that allowed pharmacies to fill opioid prescriptions one day early, which could give patients an extra two weeks' worth of opioid pills over the course of a year, Food City Employee No. 10 said.

629. The pharmacy did not keep a list of suspicious prescribers, she said.

6. *Newport, Tennessee (Food City No. 604)*

630. Newport, Tennessee (population 6,945) is the county seat of Cocke County, located on the eastern border of the State. Cocke County has had the fourth most per capita opioid prescriptions in Tennessee, or 162.6 prescriptions per 100 residents.[276]

631. Food City No. 604, 416 Eastern Plaza Center, Newport, Tennessee from 2006 to 2014 dispensed some 2,513,090 doses of opioids or 53,845,381 MME, enough at the highest bounds of the recommended MME per day (90 MME/day) for the store to supply an average of 234 opioid prescriptions per day every day for seven years.

632. According to the Washington Post, Food City No. 604 received enough opioids for 26 pills per year for each of the 9,142 men, women and children who live within five miles of this pharmacy.[277]

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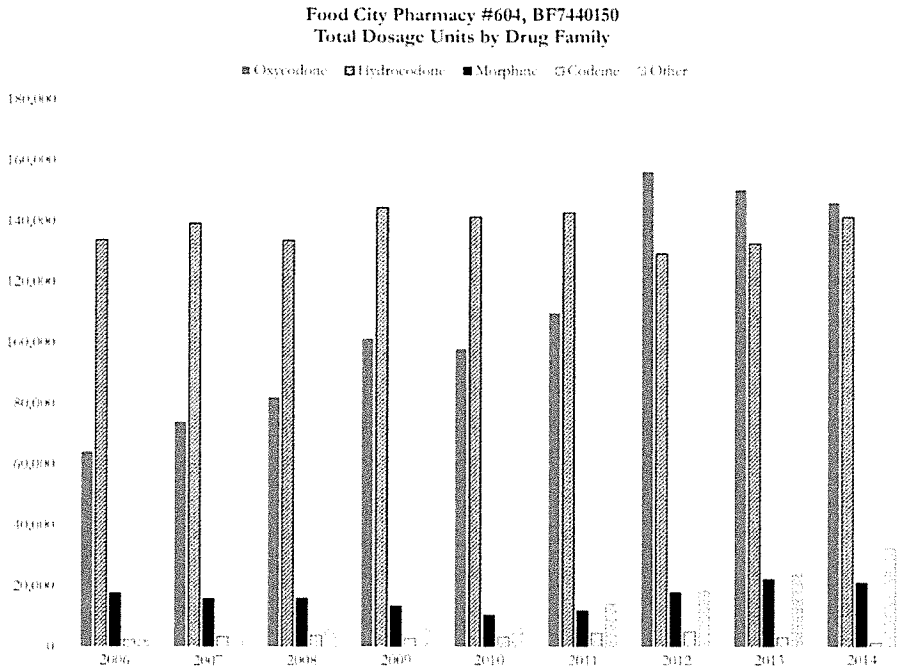
[276] Ashley Brantley, *Report card: opioid abuse in Tennessee*, BCBS of Tennessee News Center (April 16, 2019), https://bcbstnews.com/insights/report-card-opioid-abuse-in-tennessee/.

[277] Armand Emamdjomek, *et al.*, *How many pain pills went to your pharmacy?*, Washington Post (Feb. 25, 2020), https://www.washingtonpost.com/graphics/2019/investigations/pharmacies-pain-pill-map/.

633. Below is a table taken from the DEA's ARCOS database depicting the glut of opioids dispensed at this Food City which saturated Newport and Cocke County:



634. Food City Employee No. 7 joined Food City Pharmacy in 2009 as a Staff Pharmacist at Store No. 604 in Newport, Tennessee. A few years later, Food City Employee No. 7 became Pharmacy Manager of the Newport store, and he went on to be named Food City's Pharmacist of the Year two times. Food City Employee No. 7 reported to Pharmacy Services Supervisor Tom Geoghagan and Manager of Pharmacy Operations Ken Slagle. He left in 2016.

635. Food City Employee No. 7 said the Newport pharmacy "didn't fill an abundant amount of CIIs," especially in comparison to the Bearden location in Knoxville. But the Newport pharmacy did grow every year, culminating in sales of "probably close to $300,000 a month" by 2015 or 2016.

636. Food City sent out a weekly or monthly email to pharmacy employees listing the "Top 10" performing pharmacies as measured by sales and prescription volume, Food City Employee No. 7 said.

637. Food City's Bearden location in Knoxville was No. 1 in sales every week or month for several years, despite never making the top 10 list for prescription volume. Food City Employee No. 7 said he and his staff all knew the Bearden location was dispensing a high volume of opioid and controlled substance prescriptions because of its proximity to at least one pain clinic in Knoxville.

638. "They were just doing so many CIIs," he said. "Everybody knew why [the Bearden location performed well in sales]. Everybody was like, 'Well, that's the Food City that's right next to the pain clinic.' Everybody knew all those patients are just going to the [Food City] pharmacy next store."

639. The "Top 10" emails ranked pharmacies within Food City's two regional divisions: One had Knoxville and many other Tennessee stores; the other had stores in Kentucky and Virginia, along with some in Tennessee.

640. "They were definitely looking at your total sales and total prescription volume," Food City Employee No. 7 said, referring to how pharmacies were tracked by Food City's district and corporate offices.

641. Food City Employee No. 7 said the "Top 10" emails included "a little table that somebody did on Excel or something and copied and pasted into the body of the email." Food City Employee No. 7 initially said he recalled the emails including dollar figures for the top 10 performing pharmacies, but he later said he wasn't sure if the emails included dollar amounts.

642. "It was basically a competition for second place," Food City Employee No. 7 said, referring to the fact that the Bearden location was always the top-selling pharmacy. "They were way out in front."

643. Food City Employee No. 7 said he kept track of weekly prescription volume and sales for his location as a way to motivate the pharmacy to continue growing. Even after a "record-breaking week" for the Newport store, it never made the No. 1 spot on the list because the Bearden location was always the top-performing pharmacy, he said.

644. "We just kind of had the impression that No. 1 was almost unattainable," he said.

645. After authorities cracked down on the Bearden location, Food City Employee No. 7 said he "never saw them on the top 10" list again. After that, in 2015, the Bearden location ranked No. 65 in sales among all 107 Food City Pharmacy locations, Food City Employee No. 7 said.

646. Asked about whether Food City had any policies regarding procedures for dispensing controlled substances, Food City Employee No. 7 said: "They didn't really instruct me on any of that."

647. Food City Employee No. 7 said he knew the DEA advised that controlled substances should make up no more than 20% of a pharmacy's total prescriptions. And while Food City Employee No. 7 tried to maintain this rate at the pharmacy he managed, Food City did not have a policy requiring stores to maintain a specific ratio of controlled substances versus non-controlled substances, he said.

648. Although he and his staff checked the Tennessee PDMP database when filling opioid or other controlled substance prescriptions, Food City Employee No. 7 said he did not recall Food City having a policy requiring staff to check the database when filling such prescriptions.

649. In deciding whether to fill prescriptions that raised red flags, Food City Employee No. 7 said it was "a judgment call" that was "up to the pharmacist," rather than something dictated by Food City.

650. The company did not have a policy requiring pharmacy staff to document instances when a customer or prescription raised red flags, he said, or when a customer tried to fill a prescription written from a doctor who was out-of-state. "I don't think we actually documented anything," Food City Employee No. 7 said.

651. Even if a pharmacist entered notes about a customer into Food City's computer system, Food City Employee No. 7 said he did not think the computers at the company's various stores were connected, which would have made it impossible to look up notes about a customer who visited another location.

652. The Newport pharmacy did not keep a list of suspicious prescribers, he said.

653. Food City Employee No. 7 said Food City occasionally sent emails to pharmacy staff to look out for prescriptions from certain doctors.

654. "I do remember they would send out an email every once in a while saying, 'Hey, Dr. such and such in Knoxville has reported a prescription pad being stolen, so be on the lookout for any prescriptions from him,' or, 'Call and verify any prescriptions from him,'" he said.

655. Food City Employee No. 7 said Food City required employees to complete training modules on a computer program called FastTrack, but he did not remember the training included any content related to opioids and controlled substances.

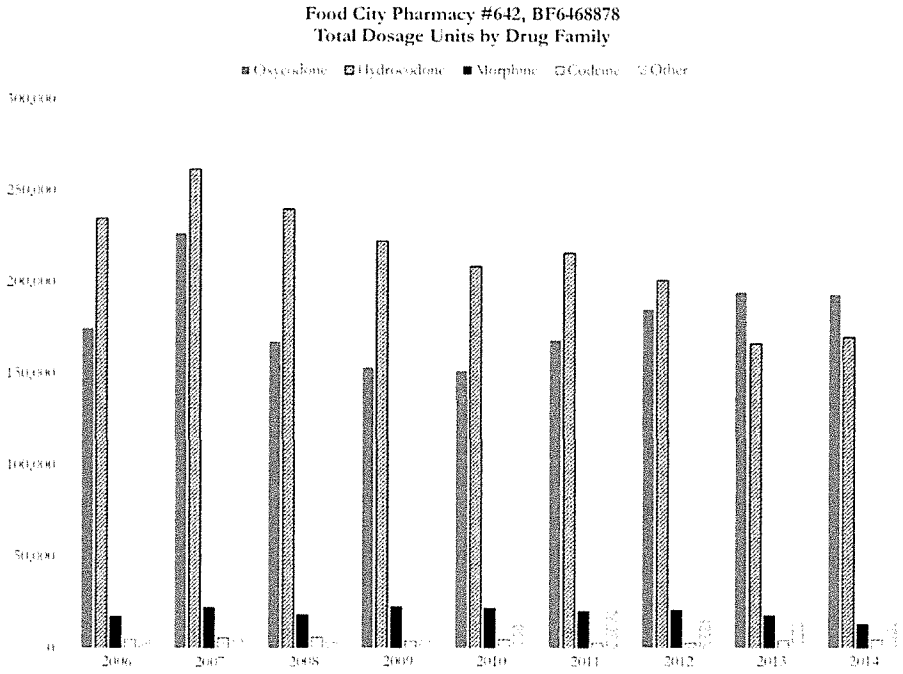
7. *Oliver Springs, Tennessee (Food City No. 642)*

656. Food City No. 642, located at 508 Tri-County Blvd., Oliver Springs, Tennessee, from 2006 to 2014 dispensed some 3,843,885 doses of opioids or an astonishing 74,566,241 MME,

enough at the highest bounds of the recommended MME per day (90 MME/day) for the store to supply an average of 324 opioid prescriptions per day every day for seven years.

657. According to the Washington Post, Food City No. 425 received enough opioids for enough for 132 pills per year for each of the 2,953 men, women and children who live within five miles of Food City pharmacy No. 642.[278]

658. Below is a table taken from the DEA's ARCOS database depicting the glut of opioids dispensed at this Food City which saturated Oliver Springs, population 3,231, overwhelmingly hydrocodone and oxycodone:



659. Food City No. 642 has seen repeated instances of opioid abuse and diversion. On May 9, 2008, Oliver Springs police officers arrested Stacy Ann Trosper for the sale and delivery of Schedule II drugs and other charges outside Food City No. 642. Trosper admitted to having

[278] Armand Emamdjomek, *et al.*, *How many pain pills went to your pharmacy?*, Washington Post (Feb. 25, 2020), https://www.washingtonpost.com/graphics/2019/investigations/pharmacies-pain-pill-map/.

OxyContin pills in her possession, according to the police report. Trosper admitted she was meeting someone at Food City and was planning to sell five of the pills. Trosper's small child was in the car with her at the time.[279]

660. When the next-door Riddle Pharmacy one day ran out of the pain pills that Dr. Delvin Littell had prescribed out of his Oliver Springs Walk-In Clinic, his patients made a run one block away on Food City pharmacy No. 642. Within two hours, 840 OxyContin pills were dispensed there. Between October 2004 and February 1, 2007, TennCare paid more than $2.3 million for pain pill prescriptions written by Littell, according to a Tennessee Bureau of Investigation affidavit.[280]

661. Littell was indicted for "excessive and/or medically unnecessary prescriptions for controlled substances" and wrote "addictive pharmaceutical prescriptions for victims that were not medically necessary and ... knew at the time of writing said prescriptions that the prescribed controlled substances were powerfully addictive, medically unnecessary and place or could have placed the victims in imminent danger of death or serious bodily injury."[281]

662. The Oliver Springs clinic had come under investigation in 2005 when complaints and concerns about activities there were brought to the attention of local law enforcement agencies.[282]

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[279] Beverly Major, *OS officers make drug arrests*, OakRidger (May 8, 2009).

[280] Beverly Majors, *Former OS doctor indicted for drug fraud*, OakRidger (Feb. 20, 2009).

[281] *Id.*

[282] *Id.*

663. On December 8, 2009, Littell, 76, pleaded guilty to TennCare fraud and reckless endangerment in Anderson County Criminal Court.[283]

664. On June 11, 2011, Felicia Sharp, 24, and Julian Langley, 35, both of 519 Cedar Lane, Oliver Springs, were arrested at Food City No. 642 for possession of Schedule II drugs for resale. During the arrest, police found plastic bags believed to be used for packaging drugs and found several prescription medications in the car including alprazolam, methadone, promethazine, morphine sulfate, oxycodone and hydrocodone. They also found three cellphones with text messages indicating the couple was selling drugs.[284]

8. *South Williamson, Kentucky (Food City No. 425)*

665. South Williamson, population 533, is located in Pike County, Kentucky, the state's easternmost county and in one of the most blighted areas in the country in terms of the opioid epidemic. Pike County has been hard hit. In 2018, there were 16 fatal overdoses related to opioids, and in 2019 that number grew by 43 percent to 23.[285]

666. Author Chris McGreal in his book AN AMERICAN OVERDOSE chronicles how the area around South Williamson, Kentucky and across the Tug Fork River in Williamson, West Virginia was overrun by opioids.[286] "Everyone seemed to come to Williamson. The accidentally addicted. The hard-core addicted looking for ever-greater highs. The teenager looking for fun who got hooked by way of the parents' medicine cabinet. Some were already addicted and saw an easy

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[283] Bob Fowler, *Anderson doctor guilty in TennCare fraud*, Knoxville News Sentinel (De. 8, 2009).

[284] Bevery Majors, OS couple arrested for allegedly selling pills, OakRidger (June 9, 2011).

[285] *Kentucky ODCP: Fatal overdoses grew in Pike in 2019* Appalachian Express (Aug. 14, 2020), https://www.news-expressky.com/news/article_a8bd6c92-de07-11ea-ada0-8fbd121550c7.html.

[286] Chris, McGreal, AMERICAN OVERDOSE: THE OPIOID TRAGEDY IN THREE ACTS (Public Affaris 2018).

way to feed their habit with what they regarded as legal heroin. Others arrived looking for medical help never having taken a drug illegally in their lives."[287]

667. According to McGreal, things got so bad they began calling the area "Pilliamson":

> People took to calling the town Pilliamson. Opinion on its streets was divided. The complaints about out-of-state cars clogging the streets rarely let up. People tried to detour past the clinics to avoid the drugged up and the dealers. But the out-of-towners were good for some local businesses, and a slice of the profits pulled in by the pharmacies – pharmacies boosted the city tax coffers.[288]

668. Food City No. 425 in South Williamson found itself in the middle of an opioid gold rush, from 2006 to 2014 dispensing some 4,373,800 doses of opioids or 28,054,147 MME, enough at the highest bounds of the recommended MME per day (90 MME/day) for the store to supply an average of 122 opioid prescriptions per day every day for seven years.

669. According to the Washington Post, Food City No. 425 received enough opioids for 251 pills per year for each of the 1,866 men, women and children who live within five miles of this pharmacy.[289]

670. Below is a table taken from the DEA's ARCOS database depicting the glut of opioids dispensed at this Food City which saturated South Williamson and Pike County, population 58,402, overwhelmingly hydrocodone:

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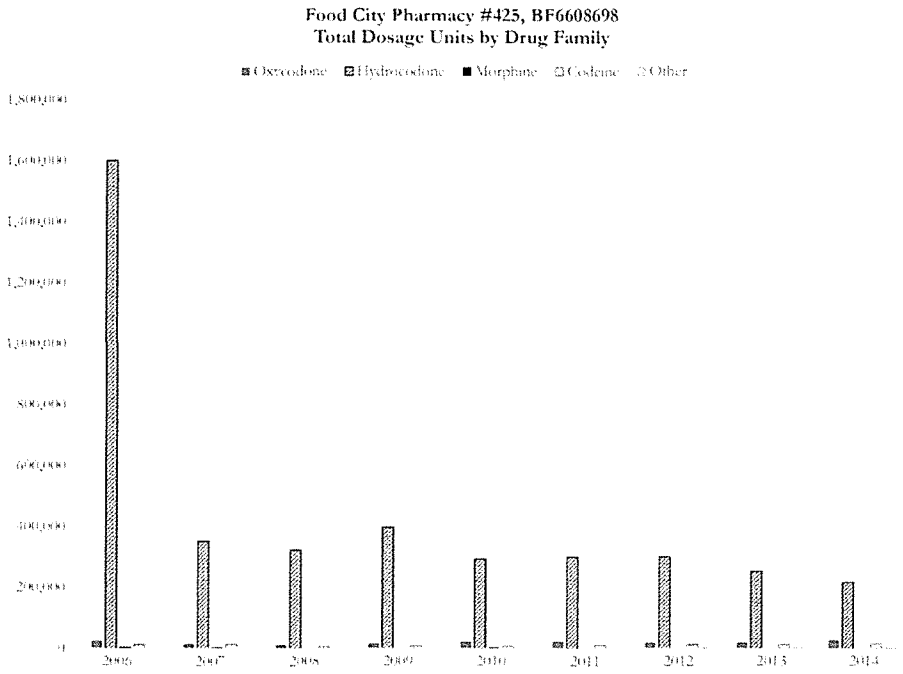
[287] *Id.* at 35.

[288] *Id.* at 36.

[289] Armand Emamdjomek, *et al.*, *How many pain pills went to your pharmacy?*, Washington Post (Feb. 25, 2020), https://www.washingtonpost.com/graphics/2019/investigations/pharmacies-pain-pill-map/.



671. Food City was clearly on notice of the widespread opioid abuse and diversion of in Pike County. On October 4, 2007, the Commonwealth of Kentucky, along with Pike County, filed suit in Pike County state court against Purdue, the Purdue Frederick Company, Inc., and other manufacturers,[290] charging that the defendant manufacturers misled medical providers and others through misrepresentations or omissions regarding the appropriate uses, risks and safety of OxyContin. In particular, the suit asserted in relevant part that, through misrepresentations and/or omissions related to the manufacture, promotion, and marketing of OxyContin, the Kentucky state Medicaid program and other state benefits programs suffered losses. The Commonwealth later in December 2015 settled with Purdue for $24 million.

[290] *See Commonwealth of Kentucky, ex rel. Jack Conway, Attorney General, and Pike County, Kentucky v, Purdue Pharma L.P., et al.*, Civil Action No. 07·Cl·1303 (Pike County Court).

672. Not only that, but Food City should also have been aware of numerous pill mill doctors operating in and around South Williamson.

673. Dr. Katherine Hoover, who later fled the country after being accused of illegally writing pain medication prescriptions, ran the Mountain Medical Care Center, in Williamson, West Virginia, directly across the Tug Fork (the Kentucky-West Virginia border) from South Williamson. According to news reports, Hoover issued more than 335,000 opioid prescriptions, more than any other doctor in West Virginia.[291]

674. Mountain Medical physician Dr. William Ryckman, P.A. Diane Shafer and office manager Myra Miller each were later sentenced to six months in federal prison for their guilty pleas to conspiring to misuse a DEA registration number.[292]

675. Dr. James Prommersberger, a podiatrist based in Delbarton, West Virginia, about a 20-minute drive from South Williamson, is facing a 79-count indictment for drug trafficking and writing suspicious prescriptions.[293] The indictment says Dr. Prommersberger improperly wrote prescriptions for and supplied controlled substances, hydrocodone, tramadol, and carisoprodol to 30 patients during a period from 2013 to 2017. The Kentucky Office of the Inspector General found that for one year from 2014-2015 Dr. Prommersberger prescribed over 1100 prescriptions,

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[291] Corky Siemaszko, *Dr. Katherine Hoover, accused of fueling West Virginia's opioid crisis, still thinks she didn't do anything wrong*, NBCNews (Sept. 24, 2018), https://www.nbcnews.com/news/us-news/dr-katherine-hoover-accused-fueling-west-virginia-s-opioid-crisis-n909366.

[292] John Raby, *Drug Addicts Can Sue Pharmacies, Doctors: West Virginia Supreme Court*, Claims Journal (May 22, 2105), https://www.claimsjournal.com/news/southeast/2015/05/22/263525.htm.

[293] Joe Gorman, *Boardman podiatrist facing 79 charges turns down plea deal*, WKBN First News27 (June 24, 2020), https://www.wkbn.com/news/local-news/boardman-podiatrist-facing-79-charges-turns-down-plea-deal/.

nearly 90 percent of which were hydrocodone. The majority of the orders in Kentucky were for quantities of 60 pills or more per month, according to investigators.[294]

676. Pikeville doctor Sai Gutti, M.D., who owned and operated five pain management clinics was among those charged on April 17, 2019. Gutti is facing eight counts of healthcare fraud for billing Medicare and Medicaid for services that were either not done or not medically necessary, specifically urine testing. Gutti's Pikeville pain clinic was raided on March 25, 2019 by the DEA. Gutti's charges are for offenses which allegedly took place between August of 2016 and March 25, 2019.[295]

677. Many of Dr. Gutti's patients were Medicare beneficiaries. During the time period 2014 through 2017, Medicare Part D plans paid some $567,746 in claims for CII and CIII drugs he had prescribed[296]:

DRUG	TOTAL MEDICARE CLAIMS	TOTAL MEDICARE COSTS ($)
FENTANYL	39	$2,018.34
GABAPENTIN	12,373	$291,967.71
HYDROCODONE-ACETAMINOPHEN	16,017	$265,992.43
MORPHINE SULFATE ER	215	$7,767.89
GRAND TOTAL	**28,644**	**$567,746.37**

[294] *Boardman podiatrist indicted in opioid prescription case*, 21WFMJ News (Feb. 18, 2019), https://www.wfmj.com/story/39932368/boardman-podiatrist-indicted-in-opioid-prescription-case.

[295] Indictment, *U.S. vs. Sai P. Gutti, M.D.*, No. 3:19-cr-22 (Apr. 11, 2019).

[296] This table compiles Medicare provider utilization and payment data available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Part-D-Prescriber.

678. On August 10, 2020, Scotty Akers, M.D., 48, a licensed ER physician, and Serissa Akers, 33, his wife and former office assistant, both of Pikeville, Kentucky, pleaded guilty to unlawfully distributing controlled substances. After Akers closed his Pike County pain clinic, Pikeville Sports, Spine & Pain Center, he began treating pain patients out of his home. According to their plea agreement, Serissa Akers exchanged prescriptions written by Dr. Akers for cash in parking lots around Pikeville. The defendants also admitted that Dr. Akers performed no physical examinations that would justify these parking-lot prescriptions, and failed to engage in other measures that prevent the abuse and diversion of opioids.[297]

679. Many of Dr. Aker's patients were Medicare beneficiaries. During the time period 2014 through 2017, Medicare Part D plans paid some $45,521 in claims for CII and CIII drugs he had prescribed[298]:

DRUG	TOTAL MEDICARE CLAIMS	TOTAL MEDICARE COSTS ($)
FENTANYL	68	$9,100.93
GABAPENTIN	160	$4,016.70
HYDROCODONE-ACETAMINOPHEN	421	$11,319.73
OXYCODONE HCL	80	$4,385.51
OXYCODONE-ACETAMINOPHEN	192	$16,698.33
GRAND TOTAL	**921**	**$45,521.20**

[297] Press Release, U.S. Department of Justice (August 10, 2020), https://www.justice.gov/opa/pr/eastern-kentucky-doctor-and-assistant-plead-guilty-unlawfully-distributing-opioids.

[298] This table compiles Medicare provider utilization and payment data available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Part-D-Prescriber.

680. Food City Employee No. 15 worked for Food City Pharmacy as Director of Pharmacy from 1999 to 2004 out of Food City's corporate headquarters office in Abingdon, Virginia. He also visited many of the company's pharmacy locations throughout Virginia, Tennessee and Kentucky.

681. Employee No. 15 recollected that Food City's Store No. 425 in South Williamson, Kentucky "bothered me more than any other store" because it filled an abnormally high amount of CIIs, many of which were prescribed by a group of about four doctors operating out of an old business or house in the town, he said.

682. "It was an absolute terror," Food City Employee No. 15 recalled of the pharmacy. One of the doctors rented a house in Williamson, a "nasty, like a one-room, little kitchen/bedroom/bathroom type thing, $300 a month," Food City Employee No. 15 said. "You would not have wanted to stay an hour in that house."

683. Food City Employee No. 15 describe the house as a "little slum" and said the doctors did not pay their water or electricity bills. One of the doctors flew to South Williamson from his or her home in Pennsylvania on Monday mornings and returned to Pennsylvania on Thursday evening or Friday. The other three doctors were not from the U.S.

684. Food City Employee No. 15 said the group of doctors was eventually "busted" in 2005 or 2006, and that the three foreign doctors were able to leave the country. Food City Employee No. 15 said he recalls the Pennsylvania doctor spent time in prison.

685. He began making regular trips to the South Williamson store because he was concerned by the volume of CIIs being filled there and the questionable doctors who were writing many of the prescriptions. On his fourth or fifth visit to the location, Food City Employee No. 15 said he realized that the amount of CIIs being sold at the store "had really picked up."

686. "The thing that clicked with me the most … they wanted to start opening the store at 8 o'clock instead of 9," he said, prompting him to ask: "I said why? [The pharmacy manager said] they have a lot of people – there's a doctor's office that opens at 7 in the morning to start seeing a lot of patients – sometimes earlier than that. When we come here at 9 o'clock, we've got people lined up outside." Jack Blackburn, who was the store manager of the South Williamson store, told Food City Employee No. 15 that there were pharmacy patients lined up for about 10 to 15 yards when he arrived to open the store each day.

687. One morning, he was at the South Williamson store at about 11:30 a.m. and noticed the pharmacy had already filled about 30 CII prescriptions, which troubled him.

688. On some days, about 60% to 70% of the prescriptions that had been filled at the South Williamson store were controlled substances, including about 30% to 40% CIIs, he remembers.

689. After realizing the abnormally high volume of CIIs were being dispensed at the South Williamson store, he went back to Food City's headquarters office in Abingdon, and spoke with Food City President and Chief Executive Officer Steve Smith, telling him that the pharmacy was "filling an unproportionate amount of controlled drugs out of that pharmacy, and the doctors [sending patients] there 'are questionable.' I said I don't know how long it's going to last or how it's going to affect the business."

690. "[President and CEO Smith] said, 'Are the doctors legitimate? Are they legitimate prescriptions?'"

691. "I said, 'They may be legitimate prescriptions and legitimate doctors, but are they a legitimate need?'"

692. "He said, 'Well, our place is to fill prescriptions. That's what we do.' … He said something about, 'We're in the pharmacy business, and if it's a legitimate prescription, we have an obligation to fill it.'"

693. Food City Employee No. 15 responded that the large number of patients receiving CII medications at the South Williamson store was making it more difficult for other customers to get their prescriptions, telling President and CEO Smith: "I said, 'Well, if you're an older lady and you're going to get your blood pressure medication and your arthritis medication … you're not going to stand in line with the clientele that we have standing in line,'" Employee No. 15 said, adding: "'I don't know if [that's] business we want. We're definitely not promoting the business that we want, that we should be getting for the long-term success of the pharmacy.'"

694. Food City President and CEO Smith replied by saying "something like, 'That will all work out,'" Food City Employee No. 15 said. "He didn't seem to be concerned. It was hard to bring it up because you already knew the answer you were going to get."

695. Another time, Food City Employee No. 15 was at the South Williamson store and pretended to be on the phone so that he could observe pharmacy staff. "Then I saw something I've never seen before in my life," he said. "They pull[ed] out baskets that had already been counted with 120 Lortab 10 and 90 Xanax [pills]. All they had to do was grab the label and put it on the bottle."

696. Food City Employee No. 15 said the pharmacy had baskets with 30 pre-filled bottles of medications such as Lortab 10 (120 pills), Xanax (90 pills), Percocet, and Soma.

697. After noticing the pre-filled bottles, he went to the pharmacy manager, a woman whose name he did not remember, asking her: "What are we going to do here? How do you feel about this?'" he said "She said, 'I feel good about this.'"

698. A few weeks later, Food City Employee No. 15 asked this same pharmacy manager how well she knew the doctors who were writing many of the CII prescriptions they were receiving. The pharmacy manager told him she knew the doctors very well. In fact, she had been at their house the previous night for dinner after she got off work.

699. "I found out they are big friends," he said, adding that the pharmacy manager would regularly go out to dinner with the doctors or on weekend trips to Gatlinburg, Pigeon Forge or the Smoky Mountains. "How am I going to [handle] a situation that I have concerns about when the pharmacist there is best friends with the doctors?"

700. Food City Employee No. 15 said he remembered the district manager who oversaw the South Williamson store walk up to him and say – in regard to all the prescriptions being dispensed there – "'That'll put me No. 1. That increased my bonus.'"

701. "Nobody seemed to care," Food City Employee No. 15 said. "Every time I'd say something, it'd fall on deaf ears."

702. During another visit to South Williamson, Food City Employee No. 15 initially spent some time in the pharmacy before returning to his vehicle and putting on a Harley Davidson T-shirt. He then sat on a bench in front of the store, had a candy bar and a beverage and began chatting with some customers who were coming to visit the pharmacy.

703. Food City Employee No. 15 asked one customer if he could get a Lortab prescription from one of the doctors operating out of the house in town. "'How's that work?'" Food City Employee No. 15 asked the customer. "'I live in Virginia – would they still let me come up here [and get the prescription]?'"

704. The customer responded: "'Hell, you got $250, he'll write you anything.'"

705. Another customer explained that new patients first had to pay a $400 "entry fee" and sign a contract. The doctors did not want to take insurance and required payment in cash.

706. He recalls that additional visits cost $200 to $250, the customer said.

707. After learning these details about the doctors sending prescriptions to the South Williamson store, Food City Employee No. 15 relayed the information to Director of Pharmacy Operations Don Clark, who had taken Dave Hardin's position. (Hardin had taken over after Food City Employee No. 15 had asked to step down from the position.)

708. "You know what he said? Nothing," Food City Employee No. 15 remembers. "Not a word. He never even opened his mouth."

709. He recalled seeing a local newspaper report about someone from South Williamson who died from a drug overdose involving Fentanyl and Lortab. A photo published with the story showed prescription bottles. "Guess where they were from?" Food City Employee No. 15 asked. "Food City Pharmacy. They showed prescription bottles in the background, and you could see it was an overdose situation. That's what made me go talk to Don Clark."

710. He at one point asked Clark how the company was going to address the abnormally high numbers of CIIs being dispensed at some of its pharmacies, like the South Williamson store.

711. "And when I did, his comment was, 'If we put something in writing, we're going to be held liable. The more we say, the more liable we're going to be. If we don't say anything at all, then we don't have any issues,'" Food City Employee No. 15 commented, adding: "They didn't want to address it."

712. Food City Employee No. 15 said he remembered talking to a pharmacy technician at the South Williamson store about the newspaper photo he had seen with an overdose victim and the Food City prescription bottles. "And she said, 'Which one are you talking about?'" he recalls,

adding: "I found out that there were a lot of people overdosing, and there were pictures in the paper – they would show medicine bottles from Food City."

713. "There were pictures in the paper that you could see Food City prescription bottles in the background," Employee No. 15 said, "or they had a picture of somebody overdosing on the street and on the sidewalk and there was a prescription bottle – or it was on a mantle in a bedroom … or on the counter or the bedstand."

714. Food City Employee No. 13 joined Food City Pharmacy in 2002 as a floating pharmacist, filling in for other pharmacists who were on vacation or when they called in sick. Food City Employee No. 13 worked at locations in Kentucky, Virginia and Tennessee (primarily Kentucky and Virginia). He worked most frequently at Store No. 425 in South Williamson, Kentucky and Store No. 437 in Harlan, Kentucky.

715. Food City Store No. 425 in South Williamson, Kentucky filled a high volume of prescriptions from a pain clinic located across the river/border in Williamson, West Virginia, Food City Employee No. 13 said, adding that he recalls one in particular run by Dr. Katherine Hoover.

716. Patients from the pain clinic typically received the same combination of four or five prescriptions each, including an opioid, a nerve pill or muscle relaxant, one or two narcotics and a blood pressure medication, he said.

717. Doctors from the pain clinic called in all of their prescriptions by phone. Prescribing doctors called the pharmacy up to four times a day. "They would call everything [in]," Employee No. 15 said. "If they saw 10 patients and they each had five [prescriptions], you're taking 50 prescriptions over the phone."

718. "I think they'd usually call in about 10, maybe again about 11:30 or 1. Then they would call in once or twice in the afternoon," Food City Employee No. 13 said, adding that this occurred every day he worked at the store.

719. "It was not unusual to get 40 or 50 prescriptions phoned in at one time, and then you get those down and it might be a little lull for a few minutes. And then they'd call in and there'd be 40 or 50 more [prescriptions] for 10 patients. It was a pretty busy store."

720. According to Food City Employee No. 13, the South Williamson store could receive 300-500 prescriptions per day. Not all of them were opioids, but a "large bulk of them would be," and they "came from that pain clinic."

721. The pharmacy filled 1,200 "or maybe even more" prescriptions from the pain clinic each week, he said.

722. Food City Employee No. 13 said the patients with prescriptions from the pain clinic "looked pretty rough. Some of the people coming in, I wondered if they were really needing all of the stuff." He said he remembers thinking, "'How can all these people need all this stuff?'"

723. Food City Employee No. 13 said he was "not totally" comfortable filling prescriptions from the pain clinic, though he said he never refused to fill a prescription. "I think that's probably one of the reasons I [found] another retail job," he said.

724. The South Williamson store typically had two pharmacists and three or four pharmacy technicians working. To keep up with the high volume of patients and prescriptions – especially the high volume of prescriptions from the pain clinic across the river – pharmacy staff pre-filled prescription bottles for the six or seven of the fastest-selling medications, including narcotics, Lortab, Xanax/Ativan, Food City Employee No. 13 said.

725. The pharmacy kept about 15-20 pre-filled bottles of each medication waiting in a box on a shelf in the area where medications were stored. "It was so busy that they would take their fast-moving products and they would fill like 30, 60, 90 pills," he said. "The prescriptions were such common numbers – 30, 60, 90, 120 – you rarely got one that wasn't one of those numbers."

726. When a customer picked up one of the prescriptions, pharmacy staff would need only to print off the prescription label and stick it on the pre-filled bottle. "I always tried to open the top and double glance, make sure what was in there was supposed to be," he said.

727. Food City Employee No. 13 said it is not common within the pharmacy industry to pre-fill prescription bottles. The only other time he remembered doing it was during his rotations at the VA (Veterans Affairs) in Birmingham, AL, which was 40 years ago.

728. Food City Employee No. 13 said he recalled a pharmacy technician who worked at the South Williamson store tell him the store had to call the state police once because customers were picking up prescriptions and selling them in the parking lot or in the store's bathroom.

729. Food City did not have any policy related to dispensing opioids and other controlled substances, Food City Employee No. 13 said.

730. Food City Employee No. 13 said Food City did not have a policy requiring pharmacy staff to enter notes in its computer system to document instances when a patient or prescription raised red flags.

731. The Food City pharmacies where Food City Employee No. 13 worked did not keep lists of suspicious prescribers.

732. Food City Employee No. 13 said that Food City wanted pharmacy staff to fill prescriptions even if they "didn't really feel the most comfortable doing it."

733. "I do think that they had the attitude, if it was a legitimate prescription, fill it, even if you didn't really feel the most comfortable doing it," he said. "That if it was legally written and all that, I think they had the attitude that they wanted you to go ahead and fill it."

734. Food City Employee No. 13 recalled that at about the time he left Food City, the company appointed Don Clark from the grocery business to oversee its pharmacy operations.

735. Food City's pharmacies were run "more like [how] you expect a grocery store" to be run, Food City Employee No. 13 said, explaining that grocery stores operate on "thin margins – and it's all about the volume. It seemed to me like it was almost the way they wanted the pharmacy run," he said.

736. Food City Employee No. 12 worked for Food City Pharmacy from spring 2008 to spring 2009 as a Pharmacy Manager and Floating Pharmacist. He worked at Store No. 425 in South Williamson, Kentucky. He also filled in occasionally at Food City Pharmacy locations in Shelbiana, Kentucky; Prestonsburg, Kentucky; and Paintsville, Kentucky. Pharmacy Manager No. 12 worked with Store Manager Jack Hatfield, and he reported to a sequence of District Managers, including Will Blevins.

737. Before Food City Employee No. 12 took over as Pharmacy Manager, the Food City No. 425 in South Williamson regularly filled prescriptions from at least four suspicious prescribers: Dr. Katherine Hoover, Dr. James Prommersberger and a tandem of nurse practitioners, Betty Karnes and Nancy Clay, he recalled.

738. Hoover saw 90 to110 patients every day, each of whom had to pay $200 to $300 in cash up front just to see her, he remembers. "The stories I've heard – you were just told a day to come back, first come first serve," Food City Employee No. 12 said. "You didn't get seen [by Hoover] until you paid your cash up front."

739. After visiting Hoover, many of the patients would come to the South Williamson Food City Pharmacy and "wait for hours – hours – for the prescriptions to be sent in [and filled]," he said.

740. Hoover prescribed a combination of Lortab 10 (120 pills), Xanax 1 (90 pills) and Soma 350 (90 pills). The South Williamson Food City dispensed easily 50 prescriptions and more likely 100 from Hoover every day, he said.

741. "Everybody in this area had heard of Hoover," Food City Employee No. 12 added. "Everybody knew what she was doing. It was an open secret."

742. Food City Employee No. 12's predecessor as Pharmacy Manager of the South Williamson store was friends with Hoover, and her husband and Hoover's husband were also friends. Food City Employee No. 12 said he did not remember the name of the Pharmacy Manager but thinks it was Donella or Donetta.

743. "And so the pharmacist [Donella or Donetta] was filling everything [Hoover] was sending in," he said. "It was a pill mill."

744. Prommersberger wrote all his patients prescriptions for 50 pills of Lortab 7.5 or Lortab 10 (the brand name for hydrocodone-acetaminophen). "That was a little excessive for a hung toenail or something," Food City Employee No. 12 said.

745. Many of Dr. Prommersberger's patients were Medicare beneficiaries. During the time period 2014 through 2017, Medicare Part D plans paid some $45,521 in claims for CII and CIII drugs he had prescribed[299]:

[299] This table compiles Medicare provider utilization and payment data available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Part-D-Prescriber.

DRUG	TOTAL MEDICARE CLAIMS	TOTAL MEDICARE COSTS ($)
GABAPENTIN	1,223	$28,969.46
HYDROCODONE-ACETAMINOPHEN	3,950	$63,993.64
OXYCODONE-ACETAMINOPHEN	45	$449.46
GRAND TOTAL	**5,218**	**$93,412.56**

746. Karnes and Clay were nurse practitioners who opened a pain management practice in South Williamson after Kentucky started allowing nurse practitioners to prescribe controlled substances, including opioids.

747. Karnes and Clay accepted only cash and no insurance, and they saw about 40-50 patients each per day. They prescribed a month's supply of Lortab (3-4 times a day) and Xanax (2-3 times a day), Food City Employee No. 12 said.

748. On most occasions, customers with prescriptions from Hoover, Prommersberger and Karnes or Clay paid entirely in cash and typically did not have insurance, Food City Employee No. 12 said.

749. With regard to filling prescriptions from Hoover and other "pill mill" prescribers, Food City Employee No. 12 said: "My impression that I got from the techs that had been working there while this was going on was Food City didn't give a crap – as long as the money was coming in."

750. When Food City Employee No. 12's predecessor left the South Williamson store, Hoover stopped sending prescription orders to the store, which meant Food City "desperately" needed a pharmacist to replace the pharmacy manager who had left, Food City Employee No. 12 said. The company offered him the job, which he accepted but with a condition.

751. "I said, 'I'm not going to fill Hoover's prescriptions,'" he said. After Food City Employee No. 12 took over in spring 2008, the South Williamson store went from filling about 100 prescriptions from Hoover each day to none at all.

752. Food City Employee No. 12 said this was disappointing to Food City management, especially because the company had remodeled the pharmacy waiting area at the South Williamson store to accommodate all of Hoover's patients. When the pharmacy was still dispensing prescriptions written by Hoover, there were so many of her patients waiting for their medications that it made it difficult for other customers to move through the store to buy groceries.

753. "They built this big waiting room to handle Hoover's patients," Food City Employee No. 12 said, adding that her patients were "disrupting" the shopping experience of other customers. "You couldn't go in there and get your bread, milk and eggs."

754. The redesigned waiting room had 30-40 seats, but the store wound up not needing all the seats after Food City Employee No. 12 refused to fill prescriptions from Hoover.

755. The loss of business from Dr. Hoover did not sit well with Food City management. "I know they were not happy about it," he said. "I heard that secondhand – that they spent all this money on the waiting room and now we have no need for it."

756. After Food City Employee No. 12 took over, he initially filled prescriptions from Prommersberger. But Food City Employee No. 12 – who would check customers' names in KAPSER, Kentucky's prescription monitoring system, along with the West Virginia equivalent – started to notice that almost every one of Prommersberger's patients were getting prescriptions from multiple doctors.

757. He then started turning away about two-thirds of Prommersberger's patients.

758. "Almost every one of his patients who were coming in were doctor shopping," he said.

759. Food City Employee No. 12 also conducted checks in KASPER and the West Virginia equivalent for customers with prescriptions written by Karnes and Clay, which showed that about one-third of their patients were also going to Hoover and Prommersberger.

760. In such cases, Food City Employee No. 12 would call either Karnes or Clay (whichever had prescribed the medication). Clay would tell him to cancel her prescription, while Karnes would say, "'Yeah, I know that. They're not going to go over there [to the other doctors] anymore. Go ahead and fill it.'"

761. Karnes later got into trouble with the DEA and lost her prescribing privileges for a time, Food City Employee No. 12 said.

762. Given Pharmacy Manager No. 12's refusal to fill prescriptions from Hoover and his practice of turning away some customers with prescriptions from what he thought were "pill mills," he said the store's prescriptions volume decreased by 30-50% after he took over.

763. "I found myself out of favor pretty quickly because I always felt it was part of – that I was turning away some of these opiates," he said. "I know they didn't like that. They wanted me to just go ahead and fill them."

764. When he started, Food City Employee No. 12 had been promised by his district manager that he would be able to transfer to a Food City store in Shelbiana, Kentucky, which is less than a mile from his home in Pikeville, Kentucky. But that offer quickly went away when the district manager who hired him left, he said, adding that he did not remember her name.

765. He was then told he would be at the South Williamson store permanently, but only in the role of pharmacist, instead of pharmacy manager. "When I was at South Williamson, I turned

away some of these – I was trying to do things the right way – and suddenly that [offer] fell through," he said. "And then I was told I was going to be there permanently, but I wouldn't be manager, and the next thing I know I find myself floating."

766. "It was just kind of like, 'They're disappointed that the numbers are down, that their cash profit's down,'" Food City Employee No. 12 said. He said it was clear that Hatfield, who had been at the store for 30 or 40 years, was not happy with him.

767. "I think they made bonus off the profit of the store, so if the pharmacy wasn't making as much money, their bonuses would go down and it made them look bad," he said, adding that Hatfield was not helpful or cooperative when Food City Employee No. 12 asked him for help with tasks at the pharmacy. Food City Employee No. 12 said he thinks Hatfield died recently.

768. He got the impression that the Smith family, which owned Food City, "had no clue" about how to run the pharmacy side of the business and leaned on Don Clark, who was Food City's director of pharmacy operations.

769. "The feeling I got was as long as he was turning good profits, they didn't give a crap about what was going on," he said. "They were just ignorant about the whole thing. They didn't understand pharmacy. They just went with him."

770. While Food City Employee No. 12 was Pharmacy Manager at the South Williamson store, he said there were rumors that Lisa Bowen, a pharmacist who previously worked at the store, wanted to come back – and that Bowen would be happy to fill prescriptions from doctors like Hoover and Prommersberger.

771. "The problems I had was with [Food City management employee] Don Clark, and I felt like everything that was coming down was coming from Don as far as getting me out of South Williamson so Lisa could take over," he said.

772. When Food City Employee No. 12 left, Bowen took over as pharmacy manager and started filling prescriptions from Prommersberger and other "pill mill" prescribers, Food City Employee No. 12 said. Bowen did not check the prescription monitoring databases to see if customers were doctor shopping. Food City Employee No. 12 said he knew this because he occasionally filled in as a floating pharmacist at the South Williamson store even after he left his pharmacy manager role there.

773. "I really felt the pressure that they were pushing me out," he said. "They knew that Lisa [Bowen] wasn't going to be so strict about what they would fill because she was working there when they were doing all the Hoover prescriptions, and she had no problem with it."

774. When Food City Employee No. 12 accepted the job as Pharmacy Manager of the South Williamson store, Food City failed to disclose to him that the FBI or DEA (he thinks it was the FBI) had served a subpoena to the store seeking records of "hundreds of prescriptions" that had been written by Hoover.

775. The prescriptions were stored in file boxes that had been moved to the back during the remodeling of the pharmacy waiting area.

776. "Nothing was in any order, and it was within a couple of days of [pharmacy technicians] showing me the subpoena that somebody from the FBI came in and was like, 'Do you have all those pulled for me?'" he said. "And I was like, 'No, I just found out a few days ago.'"

777. The FBI agent told Food City Employee No. 12 he had one week to produce the files, which the agency needed because Hoover's case was going to trial. The agent also "threatened to throw [Food City Employee No. 12] in jail" if he did not produce the files, he said. Food City Employee No. 12 and several pharmacy technicians then had to stay at the store at night and on weekends in order to produce all the required records, he said.

778. Food City Employee No. 12 reiterated that nobody from Food City told him about the subpoena during the process of hiring him for the job. He said the district manager who hired him and Don Clark knew about the subpoena. "They all had been told, but I was never told about it," he said. "It was just a bad situation."

779. Food City had no controls in place at the South Williamson store to regulate the dispensing of opioids, and Food City Employee No. 12 did not receive any training related to dispensing opioids and other controlled substances, he said. Food City Employee No. 12 said he was "never encouraged to check" the KASPER prescription monitoring database. "It was available to us, but it was never encouraged," he said.

780. Food City Employee No. 12 said the South Williamson store saw prescriptions from pill mills located in spots all across West Virginia, which was known for being home to many pill mills.

781. Food City Employee No. 11 worked for Food City Store No. 425 from 2009 to 2018 as a Pharmacy Technician and Certified Pharmacy Technician. She reported to Pharmacy Manager Lisa Bowen and then to Pharmacy Manager Bryan Fields, who reported to a sequence of changing District Managers or Pharmacy Operations Managers, including Executive Vice President Mickey Blazer and Will Blevins.

782. Pharmacy Technician Jacob West was fired in 2019 after he was caught stealing about 9,000 narcotics pills from Store No. 425 over the span of more than a year, she said, adding that security camera footage showed West stealing pills.

783. It then came to light that West had been selling the pills in exchange for "sexually natured pictures of an underage girl," she said. News reports indicate West was indicted on human

trafficking charges in September 2019; he allegedly stole 5,525 pills valued at $9,186 from the South Williamson Food City Pharmacy.[300]

784. Food City Employee No. 11 said there were warning signs about West, who had worked at the pharmacy for about four years, that went undetected by Food City.

785. "He would linger too long in the aisles, and it would be because – his excuse would be he was on his cell phone," she said. When pharmacy staff conducted pill counts for medications like Xanax and Klonopin, which occurred every three months, West "would do it a little too quickly," she added.

786. The Kentucky Board of Pharmacy revoked West's pharmacy technician license on December 4, 2019.[301]

787. Food City Employee No. 11 recalled one instance when the pharmacy was transitioning to a new system that would allow it to do automatic ordering. A pill count conducted during the transition period found a discrepancy of pills for either Xanax or Klonopin.

788. "And at first [Pharmacy Manager] Bryan [Fields] thought, 'Who's stealing?'" Food City Employee No. 11 said. "That really stuck out in my mind after [West] was caught stealing," she recalled. West "was one of the key ones to say, 'Nobody's stealing.'"

789. Fields eventually attributed the discrepancy to the system change, and the stealing allegations were dropped.

790. With regard to the pharmacy's dispensing practices, Food City Employee No. 11 said pharmacy staff usually conducted checks using KASPER, Kentucky's prescription

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[300] Chris Anderson, *Pike duo facing human trafficking charge*, Appalachian News-Express (Sept. 12, 2019), https://www.news-expressky.com/news/article_19fef0f8-d4e3-11e9-9946-4b0f13b9b3d2.html.

[301] *See* Agreed Order of Revocation, Kentucky Board of Pharmacy (December 4, 2019).

monitoring system ("Kentucky All Schedule Prescription Electronic Reporting"), or the West Virginia equivalent, given that South Williamson is located on the Kentucky-West Virginia border.

791. However, pharmacy staff did not conduct checks using KASPER or the West Virginia equivalent if the person receiving the prescription was "a very good customer" and "never gave us any trouble about filling medicine," she remembered.

792. Until only very recently, Food City did not have a policy requiring pharmacy staff to check KASPER or the West Virginia equivalent.

793. Pharmacy staff could use the notes section of a customer's profile in Food City's computer system to document that they had to refused to fill a prescription and the reasons for doing so, even though Food City did not have a policy requiring them to do so, Food City Employee No. 11 said. But making notes in a customer's profile did not guarantee that another pharmacist or technician would see the information.

794. "The notes didn't pop up [automatically]," she said. "So you would actually have to go in and manually look at the notes."

795. Store No. 425 saw suspicious prescriptions "every day," she said. She recalled seeing prescriptions from one physician who had his nurses write out stacks of prescriptions for medications like Xanax or Gabapentin and "have them ready, and all he'd have to do was sign the prescription."

796. Pharmacy staff called the physician (whose name Food City Employee No. 11 could not remember) multiple times to ask about prescriptions. "He did not care whether he wrote [the prescriptions] or not," she recalled. "You could clearly see the name of the patient was in different handwriting than what the prescription was written for. The drug was written in pretty

girly handwriting. The name and the signature were written in a doctor's handwriting, and you could not tell what it said."

797. The doctor mostly wrote prescriptions for a combination of three types of medications: Gabapentin or Lyrica; Xanax, Klonopin or Valium; and Norco, Tramadol or Tylenol-Codeine #3. "You could clearly tell he was [operating] a pill mill," Food City Employee No. 11 said. "I've heard stories that people herd in and out of his office like cattle."

798. Dr. Mohammed Mazumder, who owned Appalachian Primary Care in nearby Prestonsburg, Kentucky, was indicted on April 11, 2019, charged with directing employees who were not certified doctors to use pre-signed blank prescriptions to prescribe controlled substances to people under his name.[302] Mazumder pleaded guilty on October 17, 2019, admitting that, when he was planning to be absent from the clinic, in anticipation of patients nevertheless coming to the clinic, he pre-signed prescriptions for opioids, which later were completed by other staff members of the clinic and ultimately delivered to patients he not seen.[303]

799. Many of Dr. Mazumder's patients were Medicare beneficiaries. During the time period 2014 through 2017, Medicare Part D plans paid some $45,521 in claims for CII and CIII drugs he had prescribed[304]:

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[302] Raven Brown, *Prestonsburg doctor among those arrested in illegal prescription opioid crackdown.* WCHS8 Eyewitness NEWS (April 17, 2019), https://wchstv.com/news/local/prestonsburg-doctor-among-those-arrested-in-illegal-prescription-opioid-crackdown.

[303] Press Release, Department of Justice, *Kentucky Physician Pleads Guilty to Unlawfully Distributing Opioids* (Oct. 17, 2019), https://www.justice.gov/opa/pr/kentucky-physician-pleads-guilty-unlawfully-distributing-opioids.

[304] This table compiles Medicare provider utilization and payment data available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Part-D-Prescriber.

DRUG	TOTAL MEDICARE CLAIMS	TOTAL MEDICARE COSTS ($)
ACETAMINOPHEN-CODEINE	973	$10,962.31
GABAPENTIN	2,905	$64,545.02
HYDROCODONE-ACETAMINOPHEN	2,275	$32,030.85
OXYCODONE HCL	14	$234.46
OXYCODONE-ACETAMINOPHEN	206	$8,537.89
GRAND TOTAL	**6,373**	**$116,310.53**

800. Pharmacy staff at Store No. 425 filled prescriptions from the doctor. "If he was the doctor they went to all the time and the prescription was due that day, we would fill it," Food City Employee No. 11 explained.

801. The pharmacy did not keep a list of suspicious prescribers "because we pretty much knew who they were," she said.

802. Food City Employee No. 11 said the store saw a drastic increase in prescriptions for Norco (hydrocodone) after it was classified as a Schedule CII drug effective October 6, 2014.

803. "It seemed like as soon as it went CII, every doctor wanted to write it," she said. "It just like blew up. When you have patients that come in there and they get it every month and they don't give you any trouble – the majority of our patients didn't give us any trouble – you have a hard time refusing a prescription to someone even though it is a CII. But they come in there and they're nice and polite … In the back of your mind, you're thinking, 'Who really needs that much Norco every month?'"

804. Some prescriptions were for 90-120 pills of the drug.

805. "You either have to have cancer to be that much in pain or some kind of debilitating disease to really need that much," she said. Yet, the pharmacy would still fill these prescriptions because "you had no legitimate reason to refuse that prescription," she said.

806. When Food City Employee No. 11 first started working at the pharmacy, a woman working the register caught an "elderly lady customer" selling Norco or Lortab pills she received from the pharmacy to another customer in the parking lot. "And when I left the pharmacy, that old lady was still getting her Lortabs and her Norcos [filled there]," she said.

807. Other than training on HIPAA and Medicare, Food City Employee No. 11 received no formal training from Food City. The company did not provide any formal training on how to identify "red flags" or training specific to dealing with controlled substances, she said.

808. "I think there should be [more training]," she said. "I don't think that you should let people that you have just hired run free and clear around narcotics."

VIII. INJURY TO GOVERNMENT PROGRAMS RESULTING FROM FOOD CITY'S ACTIONS

809. Food City is a registered pharmacy which owned, operated, and was in charge of DEA-registered pharmacies throughout Georgia, Kentucky, Tennessee, and Virginia, and (a) knowingly and/or recklessly dispensed controlled substances without a valid prescription in violation of 21 U.S.C. § 842(a)(1); and (b) knowingly and/or intentionally dispensed controlled substances throughout Georgia, Kentucky, Tennessee, and Virginia outside the usual course of the professional practice of pharmacy, in violation of 21 U.S.C.§ 841(a) and corresponding state statutes.

810. Food City repeatedly failed to exercise its corresponding responsibility as a DEA registrant to ensure that controlled substances were dispensed only pursuant to prescriptions issued

for legitimate medical purposes by practitioners acting within the usual course of their professional practice. Food City pharmacists knowingly and/or recklessly ignored readily identifiable red flags that the controlled substances prescribed were being diverted, abused, or otherwise were not for legitimate medical purposes and dispensed despite unresolved red flags.

811. Food City's pharmacists dispensed controlled substances when they knew or should have known that the prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose, including circumstances where its pharmacists knew or should have known that the controlled substances were abused and/or diverted by the customer.

812. Moreover, even in instances in which a prescriber told a Food City pharmacist that a suspicious prescription had been issued for a legitimate medical purpose, Food City willfully ignored its independent, legally-mandated duty to examine the other, often glaring, evidence that the prescription had, in fact, not been issued for a legitimate medical purpose or that the prescriber had acted outside of the usual course of his or her professional practice and dispense the prescription.

813. Despite the fact that Food City knew, or had reason to know, from its own data collection databases and from red flags, including the sheer volume of opioid drugs being dispensed at numerous many of its pharmacies and to specific prescribers, that hundreds of thousands of prescriptions were not valid, it nonetheless failed to use its own readily-available and extensive information and resources from its own data bases to fulfill its obligations under the Controlled Substances Act and ensure that the prescriptions it dispensed were issued for legitimate medical purposes by practitioners acting within the usual course of their professional practice.

814. Food City knew, or had reason to know, the prescriptions were not valid and not only dispensed those prescriptions, but also failed to notify any authority of these issues. Instead,

Food City committed affirmative acts to conceal the conspiracy, such as continued filling inappropriate and medically unnecessary prescriptions for opioids. By filling these prescriptions while the conspiracy was ongoing, Food City dispensed hundreds of millions of opioid pills based on illegitimate prescriptions.

815. Government Programs have been damaged by Food City's unfair, false, misleading, or deceptive acts or practices in the conduct of the pharmaceutical business by failing to investigate, report, and cease fulfilling inappropriate or medically unnecessary opioid prescriptions in its pharmacies.

816. Government Programs have been damaged by Food City's negligent and/or intentional and reckless actions by failing to investigate or halt dispensing of inappropriate or medically unnecessary opioid prescriptions dispensed at its pharmacies.

IX. FOOD CITY UNLAWFULLY RETALIATED AGAINST RELATOR

817. Food City unlawfully terminated Relator's employment in retaliation for his whistleblowing activities.

818. As a direct result of Food City's unlawful retaliation, Relator has suffered, and continues to suffer, severe financial and psychological harm. After being terminated, Relator struggled to find a new job. The circumstances of his departure from Food City damaged Relator's reputation in as a pharmacist. Relator was unable to provide a positive referral from Food City or adequately explain the reason she was terminated.

819. To stay financially solvent during his period of unemployment, Relator was forced to deplete his savings.

820. Relator was discharged, threatened, harassed, and discriminated against by Food City because of his lawful acts in investigating and reporting compliance violations. As such,

Relator is entitled to reinstatement, two times the amount of his back pay, interest on the back pay, and compensation for all damages allowed by law, including but not limited to special damages, and damages for emotional distress, sustained as a result of his unlawful termination.

X. CAUSES OF ACTION

COUNT I

(Violation of False Claims Act, 31 U.S.C. § 3729(a)(1); 31 U.S.C. § 3729(a)(1)(A))

821. The United States incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

822. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the United States of America false or fraudulent claims for payment or approval of Opioids, in violation of 31 U.S.C. § 3729(a)(1) and 31 U.S.C. § 3729(a)(1)(A).

823. Because of Defendant's actions, the United States of America has been, and continues to be, severely damaged.

COUNT II

(Violation of False Claims Act, 31 U.S.C. § 3729(a)(2); 31 U.S.C. § 3729(a)(1)(B))

824. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

825. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used,

false records or statements material to the payment of false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(2)and 31 U.S.C. § 3729(a)(1)(B).

826. The United States of America, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid and may continue to be paying or reimbursing for Opioids prescribed to patients enrolled in Federal Programs.

827. Because of Defendant's actions, the United States of America has been, and continues to be, severely damaged.

COUNT III

(Violation of False Claims Act, 31 U.S.C. § 3729(a)(3); 31 U.S.C. § 3729(a)(1)(C))

828. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

829. Defendant knowingly conspired, and may still be conspiring, with the various health care professionals identified and alleged herein (as well as other unnamed co-conspirators) to commit acts in violation of 31 U.S.C. § 3729(a)(1) & (a)(2), and 31 U.S.C. § 3729(a)(1)(A) & (a)(1)(B). Defendant and these health care professionals committed overt acts in furtherance of the conspiracy as alleged above.

830. Because of Defendant's actions, the United States of America has been, and may continue to be, severely damaged.

COUNT IV

(Violation of False Claims Act, 31 U.S.C. § 3729(a)(7); 31 U.S.C. § 3729(a)(1)(G))

831. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

832. Food City knowingly avoided or decreased its obligation to pay or transmit money to the Government. Specifically, Food City: (i) made, used, or caused to made or used, a record or statement to conceal, avoid, or decrease an obligation to the United States; (ii) the records or statements were in fact false; and (iii) Food City knew that the records or statements were false.

833. Because of Defendant's actions, the United States of America has been, and may continue to be, severely damaged.

COUNT V

(Violation of False Claims Act, 31 U.S.C. § 3730(h))

834. Relator incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

835. Because of Relator's lawful acts in furtherance of protected activities in the investigation and reporting of fraud, Defendants discriminated against him by terminating his employment, and refusing to provide a positive reference for prospective employers.

836. Relator's termination of employment was a direct result of Defendants' retaliatory acts, causing Relator to suffer, and continue to suffer, substantial reputational, financial and psychological damage in an amount to be proven at trial.

COUNT VI

(Violation of Georgia False Medicaid Claims Act)

837. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

838. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the

Georgia Medicaid program false or fraudulent claims for payment or approval, in violation of Ga. Code Ann. § 49-4-168.1(a)(1).

839. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Georgia Medicaid program, in violation of Ga. Code Ann. § 49-4-168.1(a)(2).

840. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Georgia, or its political subdivisions, in violation of Ga. Code Ann. § 49-4-168.1(a)(7).

841. The State of Georgia, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for Opioids prescriptions for recipients of Medicaid.

842. Because of Defendant's actions, the State of Georgia and/or political subdivisions have been, and may continue to be, severely damaged.

COUNT VII

(Violation of Tennessee Medicaid False Claims Act)

843. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

844. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the State of Tennessee, or its political subdivisions, false or fraudulent claims for payment under the Medicaid program, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(A).

845. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false or fraudulent records or statements to get false or fraudulent claims under the Medicaid program paid for or approved by the State of Tennessee, or its political subdivisions, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(B).

846. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false or fraudulent records or statements to conceal, avoid or decrease an obligation to pay or transmit money to the State of Tennessee, or its political subdivisions, relative to the Medicaid program, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(D).

847. The State of Tennessee, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for Opioids prescriptions for recipients of the Medicaid program.

848. Because of Defendant's actions, as set forth above, the State of Tennessee and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT VIII

(Violation of Virginia Fraud Against Taxpayers Act)

849. Relator incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

850. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the Commonwealth of Virginia, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Va. Code Ann. § 8.01-216.3(A)(1).

851. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Commonwealth of Virginia, or its political subdivisions, in violation of Va. Code Ann. § 8.01-216.3(A)(2).

852. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth of Virginia, or its political subdivisions, in violation of Va. Code Ann. § 8.01-216.3(A)(7).

853. The Commonwealth of Virginia, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance upon the accuracy of these

claims and/or statements, paid, and may continue to pay, for Opioids prescriptions for recipients of state funded health insurance programs.

854. Because of Defendant's actions, as set forth above, the Commonwealth of Virginia and/or its political subdivisions have been, and may continue to be, severely damaged.

XI. PRAYER FOR RELIEF

WHEREFORE, Relator prays for judgment against Defendant as follows:

A. That Defendant be ordered to cease and desist from submitting any more false claims, or further violating 31 U.S.C. §§ 3729 et seq.; Ga. Code Ann. §§ 49-4-168 et seq.; Tenn. Code Ann. §§ 71-5-181 et seq.; Va. Code Ann. §§ 8.01-216.1 et seq.;

B. That judgment be entered against Defendant in the amount of each false or fraudulent claim, multiplied as provided for in 31 U.S.C. § 3729(a), plus a civil penalty of not less than eleven thousand four hundred sixty-three dollars ($11,463) or more than twenty-two thousand nine hundred twenty-seven dollars ($22,927) per false claim, as provided by 31 U.S.C. § 3729(a) and 15 C.F.R. § 63(a)(3),305 to the extent such multiplied penalties shall fairly compensate the United States of America for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

C. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the State of Georgia or its political subdivisions multiplied as provided for in Ga. Code Ann. § 49-4-168.1(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars

[305] These figures are subject to change pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. 101-410, 104 Stat. 890 (Oct. 5, 1990), as amended.

($11,000) per false claim, as provided by Ga. Code Ann. § 49-4-168.1(a), to the extent such multiplied penalties shall fairly compensate the State of Georgia or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

D. That judgment be entered in Relator's favor and against Defendant for restitution to the State of Tennessee for the value of payments or benefits provided, directly or indirectly, as a result of Defendant's unlawful acts, as provided for in Tenn. Code Ann. § 71-5-182, multiplied as provided for in Tenn. Code Ann. § 71-5-182(a)(l), plus a civil penalty of not less than five thousand dollars ($5,000) or more than twenty-five thousand dollars ($25,000) per false claim, pursuant to Tenn. Code Ann. § 71-5-182(a)(l),306 to the extent such multiplied penalties shall fairly compensate the State of Tennessee for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

E. That judgment be entered in Relator's favor and against Defendant in the amount of the damages sustained by the Commonwealth of Virginia, multiplied as provided for in Va. Code Ann. § 8.01-216.3(A), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per false claim, as provided by Va. Code Ann. § 8.01-216.3(A), to the extent such multiplied penalties shall fairly compensate the Commonwealth of Virginia for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

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[306] These figures are subject to change pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. 101-410, 104 Stat. 890 (Oct. 5, 1990), as amended.

F. That Defendant be ordered to disgorge all sums by which they have been enriched unjustly by their wrongful conduct;

G. That judgment be granted for Relator against Defendant for all costs, including, but not limited to, court costs, expert fees and all attorneys' fees incurred by Relator in the prosecution of this suit;

H. That the Court issue an order enjoining the Defendant from continuing to engage in the fraudulent conduct alleged herein; and

I. That judgment be entered in Relator's favor and against Defendants for the relief necessary to make Relator whole as a result of Defendants' unlawful discrimination, including two times the amount of back pay, interest on the back pay, and compensation for special damages sustained as a result of the discrimination, pursuant to 31 U.S.C. § 3730(h)(1)-(2); and

J. That this Court award such further relief as it deems just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all claims so triable in this action.

Dated: October 12th, 2020

By: Jerry E. Martin

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